

EXHIBIT C

**(DEFENDANTS' OBJECTIONS
TO PLAINTIFF'S EXHIBITS)**

Defendants' Objections to Plaintiff Kiley Wolfe's Exhibit List (6/17/11)

Plaintiff's exhibit list includes numerous duplicate exhibits. To the extent Defendants assert objections to one copy of any such duplicate exhibit, they incorporate by reference their objections to all such duplicate exhibits.

Additionally, Plaintiff has yet to produce to Defendants the exhibits listed below. Defendants submit these objections to Plaintiff's Exhibit List to comply with the Court's scheduling order. Defendants reserve all rights to modify their objections or to object further based upon exhibits actually received from Plaintiff. Moreover, in compliance with the Court's orders and rules, Defendants have not listed objections to exhibits other than lack of authenticity, and preserve all other objections to the exhibits listed in Plaintiff's Exhibit List, including to the extent the identifications and/or exhibits are vague, overbroad, incomplete, lack relevance (Rule 402), prejudicial, cause confusion and/or waste time (Rule 403) or contain inadmissible hearsay (Rule 802).

Exh No.	Date	Description	Defendants' Objections
1	1995	1995 Children's Motrin OTC label	
2	1996	1996 Children's Motrin OTC label	
3	1997	1997 Children's Motrin OTC label	
4	1998	1998 Children's Motrin OTC label	
5	1999	1999 Children's Motrin OTC label	
6	2000	2000 Children's Motrin OTC label	
7	2001	2001 Children's Motrin OTC label	
8	2002	2002 Children's Motrin OTC label	
9	2003	2003 Children's Motrin OTC label	
10	2004	2004 Children's Motrin OTC label	
11	2005	2005 Children's Motrin OTC label	
12	2006	2006 Children's Motrin OTC label	
12	2007	2007 Children's Motrin OTC label	
14	2008	2008 Children's Motrin OTC label	
15	2009	2009 Children's Motrin OTC label	
16	2010	2010 Children's Motrin OTC label	
17	2011	2011 Children's Motrin OTC Label	
18	1991	1991 Children's Motrin prescription label	
19	1992	1992 Children's Motrin prescription label	
20	1993	1993 Children's Motrin prescription label	
21	1994	1994 Children's Motrin prescription label	
22	1995	1995 Children's Motrin prescription label	
23	1996	1996 Children's Motrin prescription label	
24	1997	1997 Children's Motrin prescription label	
25	1998	1998 Children's Motrin prescription label	
26	1999	1999 Children's Motrin prescription label	
27	2000	2000 Children's Motrin prescription label	
28	2001	2001 Children's Motrin prescription label	

Exh No.	Date	Description	Defendants' Objections
29	2002	2002 Children's Motrin prescription label	
30	2003	2003 Children's Motrin prescription label	
31	2004	2004 Children's Motrin prescription label	
32	2005	2005 Children's Motrin prescription label	
33	2006	2006 Children's Motrin prescription label	
34	2007	2007 Children's Motrin prescription label	
35	2008	2008 Children's Motrin prescription label	
36	2009	2009 Children's Motrin prescription label	
37	2010	2010 Children's Motrin prescription label	
38	2011	2011 Children's Motrin prescription label	
39	2/6/1997	Plaintiff's birth records from St. Francis Cabrini Hospital 3330 Masonic Drive, Alexandria, La. 71301 February 6, 1987	
40		Martin's Point/Dr. Omar Mulla medical records	
41	6/1/96-6/14/96	Children's Hospital Boston medical records and statement of service 6/1/96-6/14/96 Admission	
42	6/20/96-6/22/96	Children's Hospital Boston medical records and statement of service 6/20/96-6/22/96 Admission	
43	7/9/96	Children's Hospital Boston medical records and statement of service 7/9/96 Admission	
44	12/9/96-1/8/97	CHB medical records 12/9/96-1/8/97 Admission	
45		CHB clinical laboratory reports	
46		CHB radiology studies	
47		CHB pathology reports	
48	9/2/97 - 9/8/97	Cincinnati Children's Hospital Medical Center medical records 9/2/97 - 9/8/97 Admission	
49	9/12/97-11/1/97	Cincinnati Children's Hospital Medical Center medical records 9/12/97-11/1/97 Admission	
50	3/25/98-3/27/98	Cincinnati Children's Hospital Medical Center medical records 3/25/98-3/27/98 Admission	
51	3/30/98-4/7/98	Cincinnati Children's Hospital Medical Center medical records 3/30/98-4/7/98 Admission	
52	7/1/98-7/9/98	Cincinnati Children's Hospital Medical Center medical records 7/1/98-7/9/98 Admission	
53	10/9/98-10/23/98	Cincinnati Children's Hospital Medical Center medical records 10/9/98-10/23/98 Admission	
54	11/23/98- 12/9/98	Cincinnati Children's Hospital Medical Center medical records 11/23/98- 12/9/98 Admission	
55	1/18/99-1/22/99	Cincinnati Children's Hospital Medical Center medical records 1/18/99-1/22/99 Admission	
56	1/1/03-1/3/03	Cincinnati Children's Hospital Medical Center medical records 1/1/03-1/3/03 Admission	

Exh No.	Date	Description	Defendants' Objections
57	7/10/03- 7/11/03	Cincinnati Children's Hospital Medical Center medical records 7/10/03- 7/11/03 Admission	
58	8/6/03-8/15/03	Cincinnati Children's Hospital Medical Center medical records 8/6/03-8/15/03 Admission	
59	8/10/06-8/11/06	Cincinnati Children's Hospital Medical Center medical records 8/10/06-8/11/06 Admission	
60	8/15/06-8/16/06	Cincinnati Children's Hospital Medical Center medical records 8/15/06-8/16/06 Admission	
61	8/19/06-8/22/06	Cincinnati Children's Hospital Medical Center medical records 8/19/06-8/22/06 Admission	
62		Cincinnati Children's Hospital Medical Center clinical laboratory reports	
63		Cincinnati Children's Hospital Medical Center radiology studies	
64		Cincinnati Children's Hospital Medical Center pathology reports	
65		Cincinnati Children's Hospital Medical Center statements of services/bills	
66	3/21/94 and 5/25/94	Asthma Allergy Immunology Center records/Dr. Prem Menon 3/21/94 and 5/25/94	
67	12/12/02-12/20/02	Baptist Medical Center, Jacksonville, Florida, medical records 12/12/02-12/20/02	
68		Baptist Medical Center, Jacksonville, Florida, statement of services	
69	5/12/06; 10/26/06; 11/6/06	Baton Rouge Cardiology Center, medical records and statements of services, 5/12/06; 10/26/06; 11/6/06	
70	Various	Baton Rouge Clinic records and statements – 3/2/93; 7/26/03; 9/21/93; 12/6/93; 12/23/93; 1/21/94 7/26/03; 9/21/93; 12/6/93; 12/23/93; 1/21/94; 1/31/94; 2/10/94; 8/18/94; 8/23/94; 9/18/94 10/1/09; 11/25/08 (CT head); 7/25/06; 8/7/06, 11/25/09	
71		Baton Rouge Urology Group (Mark Posner, M.D.) medical records	
72		Calais Dermatology medical records	
73		Cardiovascular Institute of the South, (Charles Daniel, M.D.) medical records and bills	
74		Pensacola Pediatrics, (Bernard Atwell, M.D.) medical records and bills	
75		Carl Luikart, 777 Hennessy Blvd, Suite 1000, Baton Rouge, La. 70808, medical records and bills	

Exh No.	Date	Description	Defendants' Objections
76		John Walker McDonald, Gastroenterology Associates, 9103 Jefferson Hwy., Baton Rouge, La. 70809, medical records and bills	
77		The Neuro Medical Center Clinic, (Dr. Gerald J. Calegan, II) 10101 Park Rowe Ave., 4th Floor, Baton Rouge, La. 70810, medical records and bills	
78		The Neuro Medical Center Clinic, (L. Allen Proctor, M.D.) 10101 Park Rowe Ave., 4th Floor, Baton Rouge, La. 70810, medical records and bills 3/17/09	
79		The Neuro Medical Center Clinic, (L. Allen Proctor, M.D.) 10101 Park Rowe Ave., 4th Floor, Baton Rouge, La. 70810, EEG and results;	
80	6/4/2006	East Jefferson General Hospital, New Orleans, La. 6/4/06 medical records and bills	
81		Robert Dillard, M.D., 515 North Ninth Ave., Pensacola, Fl. 32504, medical records and bills	
82		Nemour's Children's Clinic, 807 Children's Way, Jacksonville, FL. 32207 medical records and bills;	
83		Ear, Nose and Throat Medical Center, 5258 Dijon Drive, Baton Rouge, La. 70808, medical records and bills	
84		Northshore Regional Medical Center, 100 Medical Center Drive, Slidell, La.. 70461, medical records and bills	
85		Orange Park Medical Center, 2001 Kingsley, Orange Park, Fl. 32073, medical records, laboratory studies and bills	
86		Our Lady of the Lake Regional Medical Center, 5000 Hennessy Blvd., 70808 medical records and bills	
87		Dr. Owen Scott, The Psychology Clinic, 7936 - B Wrenwood Blvd., Baton Rouge, La., 70809, medical records and statement for services	
88		Pearl Acres Pediatrics, (Cherie G. Oertling, M.D.) 59125 N. Pearl Drive, Slidell, La. 70471, medical records and bills	
89	8/26/97- 9/2/97	Sacred Heart Hospital, 5151 N. 9th Ave., Pensacola, Fl. 32504, 8/26/97- 9/2/97 admission medical records and bills	

Exh No.	Date	Description	Defendants' Objections
90		Sacred Heart Hospital, 5151 N. 9th Ave., Pensacola, Fl. 32504, 9/11/97 Admission medical records and bills	
91		Sacred Heart Hospital, 5151 N. 9th Ave., Pensacola, Fl. 32504, 12/24/97 Admission medical records and bills	
92		Sacred Heart Hospital, 5151 N. 9th Ave., Pensacola, Fl. 32504, 1/26/98 Admission medical records and bills	
93	9/28/1997	Slidell Memorial Hospital, 1001 Gause Blvd, Slidell, La. 70458, medical records and bills, 9/28/97 Admission	
94	6/14/1999	Slidell Memorial Hospital, 1001 Gause Blvd, Slidell, La. 70458, medical records and bills, 6/14/99 Admission	
95	5/27/1997	Slidell Memorial Hospital, 1001 Gause Blvd, Slidell, La. 70458, medical records and bills, 5/27/97 Admission	
96	6/3/2003	Slidell Memorial Hospital, 1001 Gause Blvd, Slidell, La. 70458, medical records and bills, 6/3/03 Admission	
97	7/6/2003	Slidell Memorial Hospital, 1001 Gause Blvd, Slidell, La. 70458, medical records and bills, 7/6/03 Admission	
98		Dr. Steven Zuckerman, neurologist, 7777 Hennessy Blvd., Suite 405, Baton Rouge, La. 70808, medical records and bills	
99		Tulane Hospital for Children, 1415 Tulane Ave., New Orleans, La. 70112, Radiology statements, medical records and bills	
100		Tulane Hospital for Children, 1415 Tulane Ave., New Orleans, La. 70112, Transplant clinic, medical records and bills	
101		University Hospital, 234 Goodman Street, Cincinnati, OH 45219, medical records and bills 1/2/07 - 1/5/07 admission.	
102	9-Feb	Cincinnati Children's Hospital Division of Gastroenterology, medical records 2/09	
103		University Neurology, 222 Piedmont Avenue, Cincinnati, OH 45229, medical records	

Exh No.	Date	Description	Defendants' Objections
104		Ann M. Lafranca, MD, Obstetrics and Gynecology, 9000 Airline Highway, #230, Baton Rouge, Louisiana 70815, medical records and statements of services	
105		Baton Rouge Orthopedic Clinic, 8080 Bluebonnet Blvd., No. 1000, Baton Rouge, Louisiana 70810 medical records and statements of services	
106		Island Pediatrics, Dr. Shelly Hall, 4611 Highway 17, Suite 2, Orange Park, Florida 32073, medical records	
107		Sacred Heart Hospital Emerald Coast, 7800 U.S. Highway 98 West, Destin, Florida 32550, medical records	
108		Island Pediatrics, Dr. Shelly Hall, 4611 Highway 17, Suite 2, Orange Park, Florida 32073, medical records	
109		USAMS, 4301 W. Markham Street, Little Rock, AR 72205-7199, medical records	
110		Aring Neurology, 222 Piedmont Avenue, Suite 3200, Cincinnati, OH 45219, medical records	
111		Hancock Medical Center, 149 Drinkwater Road, Bay St. Louis, MS 29521, medical records and statement for services	
112		Honigan Pediatric Clinic, P.O. Box 5697, Alexandria, Louisiana 71301-5607, medical records	
113		Baton Rouge Orthopedic Clinic, 8080 Bluebonnet Blvd., No. 1000, Baton Rouge, Louisiana 70810, medical records	
114	2005	Citizens' Petition filed February 2005 with the Food & Drug Administration	
115		FDA's Response to Citizens' Petition	
116	12/14/1995	Roujeau, J., <i>Medication Use and the Risk of Stevens-Johnson Syndrome of Toxic Epidermal Necrolysis</i> , N.E. J. Med. 12/14/95	
117	Sep-98	Srivastava M., Perez-Atayde A., Jonas MM, <i>Drug-associated acute onset vanishing bile duct and Stevens-Johnson syndromes in a child</i> , Gastroenterology, September, 1998 (Volume 115, Issue 3, Pages 743-746)	

Exh No.	Date	Description	Defendants' Objections
118	Jul-78	Sternlieb, P. et al., <i>Stevens-Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen</i> , N.Y.S.J. Med., July 1978	
119	1984	McNeil's 1984 Petition of Reconsideration to the FDA regarding OTC adult ibuprofen	
120	8/12/2009	August 12, 2009 Order of the Honorable James Holderman denying the Motion <i>in Limine</i> to Exclude 1984 Petition for Reconsideration to the FDA	
121	5/19/2004	Langstaff v. McNeil, deposition of Anthony Temple, M.D., 5/19/04	
122		Weisman, Howland, Goldfrank, IBUPROFEN: AN ANALYSIS OF SAFETY AND EFFICACY	
123		Boston University Fever study records regarding two cases of SJS	
124		McNeil records regarding two cases of Boston University Fever Study	
125	6/30/2008	N.T. of Anthony Temple, <i>Johnson v. Johnson & Johnson</i> , No. TC018540, Ca. Super. Ct., 6/30/08	
126		McNeil Consumer Products Company Clinical Study Report from the Boston University Fever Study	
127		Dolermin Ibuprofen Juice Label (Germany)	Lacks authentication (Rule 901)
128	8/24/2006	Letter (8.24.06) of William Balistreri	
129		Medical Records and statements of services of William Balistreri	
130	6/30/2008	N.T. <i>Johnson v. Johnson & Johnson</i> , No. TC018540, Ca. Super. Ct., 6/30/08	
131		N.T. from Karen Robinson v. McNeil, (N.D. IL 2009)	
132		N.T. from Brianna Maya v. McNeil, (Phila. Ct. Common Pleas 2011)	
133	9/30/2010	Testimony of Mr. William C. Weldon, Chairman and Chief Executive Officer at Johnson & Johnson before the Commission on Oversight and Government Reform in at the United States House of Representatives on September 30, 2010	

Exh No.	Date	Description	Defendants' Objections
134	9/30/2010	Testimony of Colleen Goggins before the Commission on Oversight and Government Reform in at the United States House of Representatives on September 30, 2010	
135	5/27/2010	Testimony of Colleen Goggins, Worldwide Chairman of Johnson & Johnson's Consumer Products Division before the Commission on Oversight and Government Reform in at the United States House of Representatives on May 27, 2010	
136		Deposition of Bernard Atwell, M.D.	
137		Exhibit 1- Subpoena to Dr. Atwell	
138		Exhibit 2- Dr. Atwell's file regarding Kiley Wolfe	
139		Deposition of William Balistreri, M.D. (Parts 1&2)	
140		Exhibit 1- C.V. of William Balistreri, M.D.	
141		Exhibit 2- Letters re deposition and notice of deposition	
142	8/24/2006	Exhibit 3-August 24, 2006 letter from Dr. Balistreri to William Wolfe	
143	12/9/1996	Exhibit 4- Kiley Wolfe Clinic Sheet dated December 9, 1996	
144	9/8/97	Exhibit 5- Discharge Summary from Cincinnati Children's Hospital dated 9/8/97	
145	11/1/1997	Exhibit 6-Discharge Summary from Cincinnati Children's Hospital dated 11/1/97	
146	4/7/1998	Exhibit 7-Discharge Summary from Cincinnati Children's Hospital dated 4/7/98	
147	7/9/1998	Exhibit 8-Discharge Summary from Cincinnati Children's Hospital dated 7/9/98	
148	1/12/1998	Exhibit 9-Operative Report from Cincinnati Children's Hospital dated 1/12/98	
149	12/9/1998	Exhibit 10-Discharge Summary from Cincinnati Children's Hospital dated 12/9/98	
150	1/22/1999	Exhibit 11- Discharge Summary from Cincinnati Children's Hospital dated 1/22/99	
151	8/1/2003	Exhibit 12- Discharge Summary from Cincinnati Children's Hospital dated 8/1/03	
152		Exhibit 13-Discharge Summary from Cincinnati Children's Hospital dated 8/11/06	
153		Exhibit 14- Boston Children's Hospital Clinical Laboratory Report	

Exh No.	Date	Description	Defendants' Objections
154	7/15/96	Exhibit 15- Surgical Pathology Report from Boston Children's Hospital dated 7/15/96	
155	Jun-96	Exhibit 16- Children's Hospital Admission H&P Form dated 6/96	
156	27-May-97	Exhibit 17- Letter from Dr. Balistreri to Dr. Atwell dated May 27, 1997	
157		Exhibit 18- Case Report: "Drug-Associated Acute-Onset Vanishing Ble Duct and Stevens-Johnson Syndromes in a Child."	
158		Exhibit 19- Photograph of Kiley Wolfe and Dr. Balistreri	
159	9/97	Exhibit 20- Child Life Note from Cincinnati Children's Hospital dated 9/97	
160	1/13/2010	Exhibit 21- ULT Liver Transplant with Doppler Report dated 1/13/10	
161		Exhibit 22- Chapter from Liver Disease in Children, "Drug Induced Liver Disease"	
162		Exhibit 23- Various progress notes on Kiley Wolfe	
163		Deposition of Stephen Gellis, M.D.	
164		Exhibit 1- Notice of Deposition	
165		Exhibit 2- C.V. of Stephen Gellis, M.D.	
166	6/3/1996	Exhibit 3- Consultation Request/Report (6/3/96)	
167		Exhibit 4- Case Report: "Drug-Associated Acute-Onset Vanishing Ble Duct and Stevens-Johnson Syndromes in a Child."	
168		Exhibit 5- Children's Motrin package and labeling	
169		Exhibit 6- "Medication Use and the Risk of Stevens Johnson Syndrome or Toxic Epidermal Necrolysis."	
170		Deposition of Sandip Godambe, M.D.	
171		Exhibit 1- Subpoena	
172		Exhibit 2- C.V. of Sandip Godambe, M.D.	
173		Exhibit 3- Article: "Effectiveness of oxycodone, ibuprofen, the combination in the initial management of orthopedic injury-related pain in children"	
174		Exhibit 4- Excerpts from chart from Boston Children's Hospital	
175		Deposition of Maureen Jonas, M.D.	
176		Exhibit 1- Amended Notice of Deposition	
177		Exhibit 2- C.V. of Maureen Jonas, M.D.	

Exh No.	Date	Description	Defendants' Objections
178		Exhibit 3- Maureen Jonas' file on Kiley Wolfe including records, case report and medical literature reviewed by Maureen Jonas	
179		Exhibit 4- Boston Children's Hospital Records	
180		Exhibit 5- Excerpts from Boston Children's Hospital Records	
181		Exhibit 6- Case Report: "Drug-Associated Acute-Onset Vanishing Ble Duct and Stevens-Johnson Syndromes in a Child."	
182	5-Aug-96	Exhibit 7- Maureen Jonas' Note of August 5, 1996	
183		Exhibit 8- Surgical Pathology Report for liver biopsy	
184	23-Jul-96	Exhibit 9- Maureen Jonas' Note of July 23, 1996	
185		Exhibit 10- Maureen Jonas' Note of September 3, 1996	
186	2/3/1997	Exhibit 11- Maureen Jonas' Note of February 3, 1997	
187		Exhibit 12- 5/27/97 letter to Dr. Atwell from Dr. Balistreri	
188	9/2/97-9/8/97	Exhibit 13- Discharge Summary from Cincinnati Children's Hospital Medical Center (9/2/97-9/8/97)	
189	8/24/2006	Exhibit 14- 8/24/06 letter from Dr. Balistreri to William Wolfe	
190		Exhibit 15-Liver disease flowsheet	Lacks authentication (Rule 901)
191	3/31/1995	Exhibit 16- Medwatch Report (3/31/95)	
192	9/22/1998	Exhibit 17- Medwatch Report (9/22/98)	
193		Exhibit 18- Children's Motrin Suspension Packaging (LFR00339457-LFR00339459)	
194		Exhibit 19- Package insert for Motrin	
195	8/20/1997	Exhibit 20- 8/20/97 letter to Dr. Atwell from Dr. Balistreri	
196		Deposition of Omar Mulla, M.D.	
197		Exhibit 1- Chart of Omar Mulla, M.D./ Martin's Point Pediatrics	
198	5/2/9/96	Exhibit 2- Progress note of 5/2/9/96	
199	8/24/2006	Exhibit 3- 8/24/06 letter from Dr. Balistreri to William Wolfe	

Exh No.	Date	Description	Defendants' Objections
200		Exhibit 4- Case Report: "Drug-Associated Acute-Onset Vanishing Ble Duct and Stevens-Johnson Syndromes in a Child."	
201	23-Jul-96	Exhibit 5- Maureen Jonas' Note of July 23, 1996	
202		Exhibit 6- Excerpts from Janet Leland's deposition	
203		Exhibit 7- Janet Leland's journal	
204		Exhibit 8	
205	7/22/1996	Exhibit 9- Medwatch Report (7/22/1996)	
206	8/21/1996	Exhibit 10- Medwatch Report (8/21/96)	
207		Exhibit 11- Excerpts from Maureen Jonas' deposition	
208	9/2/1997	Exhibit 12- Cincinnati Children's Hospital Medical Center Hospital Admission History and Physical (9/2/97)	
209	9/2/97-9/8/97	Exhibit 13- Discharge Summary from Cincinnati Children's Hospital Medical Center (9/2/97-9/8/97)	
210	3/30/98-4/7/98	Exhibit 14- Discharge Summary from Cincinnati Children's Hospital Medical Center (3/30/98-4/7/98)	
211	3/24/1998	Exhibit 15- Medical Short Stay Form from Cincinnati Children's Hospital Medical Center (3/24/98)	
212		Deposition of Antonio Perez-Atayde, M.D.	
213		Exhibit 1- Notice of Deposition	
214		Exhibit 2- C.V. of Antonio Perez-Atayde, M.D.	
215		Exhibit 3- Composite of photographs from liver biopsy	
216		Exhibit 4- Case Report: "Drug-Associated Acute-Onset Vanishing Ble Duct and Stevens-Johnson Syndromes in a Child."	
217		Exhibit 4A-Photograph from liver biopsy	
218		Exhibit 4B- Photograph from liver biopsy	
219		Exhibit 4C- Photograph from liver biopsy	
220		Exhibit 4D- Photograph from liver biopsy	
221		Exhibit 5-Liver biopsy report	
222	2006	Exhibit 6- Navarro, Victor, et al., The New England Journal of Medicine, "Drug Related Hepatotoxicity," 354:7, pp. 731-739 (2006)	

Exh No.	Date	Description	Defendants' Objections
223	2004	Exhibit 7- Taghian, M., et al., Journal of Pediatrics, "Acute Vanishing Bile Duct Syndrome After Ibuprofen Therapy in a Child," pp. 273-276 (2004)	
224	2004	Exhibit 8- Choi, J., et al., Korean Pediatr., "A Case of Stevens-Johnson Syndrome Plus Vanishing Bile Duct Syndrome Associated with Ibuprofen Use." Vol.45, pp. 1146-1149 (2004)	
225		Deposition of Eric Pierce, M.D.	
226		Exhibit 1- Notice of Deposition	
227		Exhibit 2- Folder entitled "Wolfe Care"- containing records from Children's Hospital Boston, Case Report, summary of Kiley Wolfe's care, Articles: "Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis Spectrum of Disease" and "Erythema Multiforme Major (Stevens-Johnson Syndrome) and Toxic Epidermal Necrolysis"	
228		Exhibit 3- Summary of Kiley Wolfe's care and C.V. of Eric Pierce	
229		Deposition of Maya Srivistava, M.D.	
230		Exhibit A- Amended Notice of Deposition	
231		Exhibit B- C.V. of Maya Srivistava	
232		Exhibit C- Drafts and Notes for Case Report	
233		Exhibit D- Excerpts from Kiley Wolfe's Medical Records	
234	8/5/1996	Exhibit E- Maureen Jonas' Note of August 5, 1996	
235	7/23/1996	Exhibit F- Maureen Jonas' Note of July 23, 1996	
236		Exhibit G- Case Report: "Drug-Associated Acute-Onset Vanishing Ble Duct and Stevens-Johnson Syndromes in a Child."	
237	9/23/1998	Exhibit H- September 23, 1998 letter from McNeil to Dr. Srivastava enclosing Medwatch Report of 9/22/98	
238		Exhibit I- Boston Children's Hospital Chart	
239		Exhibit J- Surgical Pathology Report for liver biopsy	
240		Exhibit K-excerpt from Boston Children's Hospital chart	

Exh No.	Date	Description	Defendants' Objections
241		Exhibit L- Case Report- "Efficacy of Early Immunosuppressive Therapy in a Child with Carbamazepine- Associated Vanishing Bile Duct and Stevens-Johnson Syndromes."	
242	2004	Exhibit M -Taghian, M., et al., Journal of Pediatrics, "Acute Vanishing Bile Duct Syndrome After Ibuprofen Therapy in a Child," pp. 273-276 (2004)	
243		Exhibit N – Liver Disease Flow Sheet	
244		Deposition of Robert Sundel, M.D.	
245		Exhibit 1- C.V. of Robert Sundel, M.D.	
246		Exhibit 2- Boston Children's Hospital Chart	
247	7/23/1996	Exhibit 3- Maureen Jonas' Note of July 23, 1996	
248		Exhibit 4- Surgical Pathology Report for liver biopsy	
249		Exhibit 5- Case Report: "Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child."	
250		Exhibit 6- FDA Response to Citizen's Petition	
251		Exhibit 7- Article "Stevens-Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen"	
252		Exhibit 8- Article "Toxic Shock Syndrome or Toxic Epidermal Necrolysis?"	
253		Deposition of John Troccoli, M.D.	
254		Exhibit 1- Notice of Deposition	
255		Exhibit 2- C.V. of John Troccoli, M.D.	
256		Exhibit 3- Dermatology consult reports and progress notes	
257		Exhibit 4- Section "Erythema Multiforme" from Textbook, Dermatology and General Medicine, Sixth	
258		Edition 5- Case Report: "Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child."	
259	2003	Edition 6- Handwritten notes of John Troccoli, M.D., photocopies from "Synopsis of Pediatric Dermatology" and "Dermatology and General Medicine, Edition VI, 2003"	
260		Exhibit 7- Excerpts from Boston Children's Hospital Chart	
261		Deposition of Jessica Kahn, M.D.	
262		Exhibit 1- Notice of Deposition	

Exh No.	Date	Description	Defendants' Objections
263		Exhibit 2- C.V. of Jessica Kahn, M.D.	
264		Exhibit 3- Various Documents	
265		Exhibit 4- Progress Notes from Boston Children's Hospital	
266		Exhibit 5- Discharge Summary from Boston Children's Hospital	
267		Exhibit 6- Case Report: "Drug-Associated Acute-Onset Vanishing Ble Duct and Stevens-Johnson Syndromes in a Child."	
268	8/24/2006	Exhibit 7- August 24, 2006 letter from Dr. Balistreri to William Wolfe	
269		Deposition of Kiley Wolfe	
270		Exhibit A- Plaintiff's Federal Rule 26(a) Disclosures	
271		Exhibit B- Plaintiff's Responses to Defendant, McNeil Consumer Healthcare's First Request for Production of Documents	
272		Exhibit C- Plaintiff's Responses to Defendant McNeil Consumer Healthcare's First Set of Interrogatories	
273	10/22/2007	Exhibit D- Letter from Messa and Associates dated October 22, 2007	
274		Exhibit E- Supplemental Responses to Discovery from Plaintiffs	
275		Exhibit F- Letter in lieu of formal response to request for supplemental responses to McNeil's discovery requests	
276		Exhibit G- Letter in lieu of formal response to request for further supplementation of certain responses	
277		Deposition of William Wolfe	
278		Exhibit H- William Wolfe's notes	
279		Exhibit I- Notice of Deposition	
280		Deposition of Janet Leland	
281		Exhibit J- Notice of Deposition	
282		Exhibit K- Martin's Point Pediatrics Progress Notes	
283		Exhibit L- Janet Leland's journal	
284		Deposition of Peter Bell	
285		Exhibit 1- C.V. of Peter Bell	
286		Exhibit 2- C.V. of Peter Bell	

Exh No.	Date	Description	Defendants' Objections
287		Exhibit 3-“Medication Use and the Risk of Stevens Johnson Syndrome or Toxic Epidermal Necrolysis.”	
288	2/1/1995	Exhibit 4- Medwatch Report (2/1/95)	
289	3/31/1995	Exhibit 5- Medwatch Report (3/31/95)	
290	5/15/1995	Exhibit 6- Medwatch Report (5/15/95)	
291	11/10/1997	Exhibit 7- Medwatch Report (11/10/97)	
292	9/22/1993	Exhibit 8- Medwatch Report (9/22/98)	
293	10/29/1993	Exhibit 9- 10/29/93 Memo from W.A. Vernon to Peter Bell re proposed dosing for Children’s Motrin OTC Switch	
294		Exhibit 10- Parent Q&A form	
295		Deposition of Douglas Chia	
296		Exhibit 1- Affidavit of Douglas Chia	
297	9/30/2010	Exhibit 2- Testimony of Mr. William Weldon before the U.S. House of Representatives (9/30/10)	
298	9/30/2010	Exhibit 3- Testimony of Colleen Goggins before the U.S. House of Representatives (9/30/10)	
299	9/16/2010	Exhibit 4- Letter of 9/16/10 from Congress to Mr. William Weldon requesting his testimony at the September 30, 2010 hearing, and e-mails regarding silent recall.	
300	6/12/2009	Exhibit 5- CSCS Motrin Purchase Project (June 12, 2009)	
301		Deposition of Mary Joan Denisco, Pharm D	
302		Exhibit 1- C.V. of Mary Joan Denisco	
303		Exhibit 2- BUFS Enrollment/Consent Form (MC074198)	
304		Exhibit 3- BUFS Questionnaire (MC074199-MC074200)	
305		Exhibit 4-BUFS Questionnaire (MC74201-MC074202)	
306	12/20/1990	Exhibit 5- 12/20/90- Protocol: An Assessment of the Safety of Pediatric Ibuprofen (MC074186-MC074197)	
307		Exhibit 6- Data Listing Protocol (MC044005-MC044008)	
308		Exhibit 7- McNeil Consumer Products Company Clinical Study Report Phase IV- An Assessment of the Safety of Pediatric Ibuprofen (Boston University Fever Study)(MC74066-MC74185)	

Exh No.	Date	Description	Defendants' Objections
309		Exhibit 8- Excerpts from Denisco Deposition in Langstaff v. McNeil	
310	7/27/1995	Exhibit 9- Children's Motrin Suspension Final Printed Labeling (7/27/95)(LFR003467-LFR0334689)	
311		Exhibit 10- Excerpts from Denisco Deposition in Johnson v. Johnson & Johnson	
312	1991	Exhibit 11- 1991 PDR	
313	1993	Exhibit 12- 1993 PDR	
314	1994	Exhibit 13- 1994 PDR	
315	1996	Exhibit 14- 1996 PDR	
316	3/30/2004	Exhibit 15- 3/30/04 e-mail regarding Review Motrin Rx Suspension Label for FDA Response (MOT00004724)	
317		Deposition of Tiziana Fox, PharmD	
318		Exhibit 1- CV of Tiziana Fox	
319		Exhibit 2- Adverse Event Routing Form (9/04)(LM001045)	
320	9/22/1998	Exhibit 3- Medwatch Report (9/22/98)	
321		Exhibit 4- Case Report: "Drug-Associated Acute-Onset Vanishing Ble Duct and Stevens-Johnson Syndromes in a Child."	
322	3/31/1995	Exhibit 5- Medwatch Report (3/31/95)	
323	3/19/1998	Exhibit 6- Medwatch Report (3/19/98)	
324		Exhibit 7- Medwatch Report (11/10/97)	
325		Exhibit 8- Excerpts from Fox Deposition in Johnson v. Johnson & Johnson	
326		Exhibit 9- Excerpts from Kiley Wolfe's chart from Boston Children's Hospital	
327		Exhibit 10- Children's Motrin Suspension Box (MC01A001487)	
328		Deposition of Willie Pagsuyin	
329		Exhibit 1- Notice of Deposition	
330		Exhibit 2- CV of Willie Pagsuyin	
331		Exhibit 3- Current CV of Willie Pagsuyin	
332		Exhibit 4- Objections to Notice of Deposition	
333		Exhibit 5- Excerpts from Langstaff Deposition	
334	1991	Exhibit 6- 1991 PDR	
335	1992	Exhibit 7- 1992 PDR	
336	1993	Exhibit 8- 1993 PDR	
337	1994	Exhibit 9- 1994 PDR	

Exh No.	Date	Description	Defendants' Objections
338	11/14/1994	Exhibit 10-11/14/94 Facsimile to Vivian Chester from Susan Guckenheimer regarding Motrin Label	
339	3/31/1995	Exhibit 11- Medwatch Report (3/31/95)	
340	5/31/1984	Exhibit 12-5/31/84 Letter to Robert Temple re Ibuprofen- Summary Basis of Approval	
341		Exhibit 13- Children's Motrin Suspension Final Printed Labeling	
342		Exhibit 14- Trade and Government Memos	
343		Exhibit 15- "Ibuprofen: Analysis of Safety and Efficacy"	
344		Exhibit 16- FDA Regulations	
345		Exhibit 17- 24 C.F.R. § 314.50	
346		Exhibit 18- Excerpts from Willie Pagsuyin testimony in Johnson v. Johnson & Johnson	
347	15/15/04	Exhibit 19- 1/15/10 FDA Warning letter to McNeil	
348		Exhibit 20- 21 C.F.R. § 312.32	
349		Lynn Pawelski Deposition	
350		Exhibit 6- Affidavit of Lynn Pawelski	
351		Exhibit 7- FDA Response to Citizen's Petition	
352		Exhibit 8- Excerpt of Pawelski testimony from Johnson v. Johnson & Johnson	
353		Exhibit 9- Excerpt of Pawelski testimony from Johnson v. Johnson & Johnson	
354		Exhibit 10- Excerpt of Pawelski testimony from Johnson v. Johnson & Johnson	
355		Exhibit 11- Defendants' Rule 26(a)(2) Expert Reports and Disclosures	
356		Deposition of Laura Reel Plantz	
357		Exhibit 1- C.V. of Laura Reel Plantz	
358	9/22/1998	Exhibit 2- Medwatch Report (9/22/98)	
359		Exhibit 3- Case Report: "Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child."	
360	9/23/1998	Exhibit 4-9/23/98 letter from McNeil to Dr. Srivastava re: Case Report: "Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child."	
361		Exhibit 5- Routing Sheet (MC074035-MC074036)	
362		Deposition of Anthony Temple, M.D.	

Exh No.	Date	Description	Defendants' Objections
363		Exhibit 1- "Medication Use and the Risk of Stevens Johnson Syndrome or Toxic Epidermal Necrolysis."	
364		Exhibit 2- Children's Motrin Cold Article from Motrin.com	
365	7/22/96 and 8/21/96	Exhibit 3- Medwatch Reports (7/22/96 and 8/21/96)	
366		Exhibit 4- Letter from Dr. Balistreri to William Wolfe	
367		Exhibit 5- Case Report: "Drug-Associated Acute-Onset Vanishing Ble Duct and Stevens-Johnson Syndromes in a Child."	
368	1991	Exhibit 6- 1991 PDR	
369	1993	Exhibit 7- 1993 PDR	
370	1994	Exhibit 8- 1994 PDR	
371	1995	Exhibit 9- 1995 PDR	
372	1996	Exhibit 10- 1996 PDR	
373	3/31/1995	Exhibit 11- Medwatch Report (3/31/95)	
374	5/15/1995	Exhibit 12- Medwatch Report (5/15/95)	
375	2/1/1995	Exhibit 13- Medwatch Report (2/1/95)	
376	11/10/1997	Exhibit 14- Medwatch Report (11/10/97)	
377	5/28/1996	Exhibit 15- Medwatch Report (5/28/96)	
378		Exhibit 16- Excerpt of Dr. Temple Testimony in Zundel v. Johnson & Johnson	
379		Exhibit 17- Children's Motrin Suspension Box (MC01A001487)	
380		Document sent by Rudolph Widmark, FDA review officer "a patient should be warned to discontinue NSAIDS should the develop any rash or fever without alternative explanation or mucosal symptoms" referenced in Temple's deposition at pp. 51 and 55	Lacks authentication (Rule 901)
381		Deposition of Richard Vezina	
382		Exhibit 1- Subpoena	
383		Exhibit 2- Boston University Fever Study Enrollment/Consent Form	
384		Exhibit 3- Boston University Fever Study Enrollment/Consent Form	
385	12/20/1990	Exhibit 4- 12/20/90- Protocol: An Assessment of the Safety of Pediatric Ibuprofen (MC070223)	

Exh No.	Date	Description	Defendants' Objections
386	2/12/1993	Exhibit 5- 2/12/93 Questionnaire for Boston University Fever Study (MOT00000765-MOT0000766)	
387		Exhibit 6- Data Listing Protocol (in color) (MC044005-MC044008)	
388		Exhibit 7- Data Listing Protocol (MC044005-MC044008)	
389		Exhibit 8- Subpoenas and Notices of Deposition to Richard Vezina	
390		Exhibit 9- Objections to Subpoena	
391		Exhibit 10- Letter regarding deposition	
392	12/20/1990	Exhibit 11-12/20/90- Protocol: An Assessment of the Safety of Pediatric Ibuprofen (MC01A000477-MC01A000493)	
393	6/11/1992	Exhibit 12A- 6/11/92- Letter to John Harter at FDA regarding OTC Switch of Pedia-Profen with attachments (MC12A001041-MC12A001068; MC070840-MC070852)	
394	6/11/92	Exhibit 12B- 6/11/92- Letter to John Harter at FDA regarding OTC Switch of Pedia-Profen with attachments (MC070811-MC070852)	
395		Exhibit 13- Notice of Deposition in the <i>Gaines</i> case	
396	11/1/1993	Exhibit 14- 11/1/93- BUFS Draft of Final Report (MC070647-MC070737)	
397	12/22/1993	Exhibit 15- 12/22/93-McNeil Consumer Products Company-Clinical Study Report- Phase IV- An Assessment of the Safety of Pediatric Ibuprofen (MC074066-MC074491)	
398		Exhibit 16- Appendix 1-Supplementary Tables-BUFS (MC074131-MC074182)	
399		Exhibit 17- Appendix 3- Protocol, Enrollment Form and Questionnaire, CVs for Drs. Mitchell and Lesko (MC074185-MC04213)	
400		Exhibit 18- Appendix 5- Tabulation of Individual Response Data	
401		Exhibit 19- Patient Data Listing for Study 90-056-Children's Motrin Ibuprofen Suspension (MOT-00000760-MOT00000761)	
402		Exhibit 20- BUFS Follow-Up (A00000111)	
403		Exhibit 21- BUFS Questionnaire- Alexander Bordeaux (BFSQ0086719-BFSQ0086720)	
404		Exhibit 22- McNeil Cross- Notice of Deposition	

Exh No.	Date	Description	Defendants' Objections
405		Exhibit 23- BUFS Follow-Up (A00001106)	
406		Deposition of Moshe Ardit, M.D.	
407		Exhibit 1- Notice of Deposition	
408		Exhibit 2- List of records reviewed	
409		Exhibit 3- C.V. of Moshe Ardit	
410	6/1/96-6/14/96	Exhibit 4- Children's Hospital Boston records (6/1/96-6/14/96)	
411	12/9/96-1/8/97	Exhibit 5- Children's Hospital Boston records (12/9/96-1/8/97)	
412		Exhibit 6- Compilation of materials reviewed (deps and records)	
413		Deposition of Laura Bix, Ph.D.	
414		Exhibit 1- Notice of Deposition	
415		Exhibit 2- CD with Documents sent by to Laura Bix from Plaintiff's counsel	
416		Exhibit 3- C.V. of Laura Bix	
417		Exhibit 4- CD of depositions from other cases against McNeil	
418		Exhibit 5- Index of depositions from other cases against McNeil	
419		Exhibit 6- Printouts from www.stevensjohnsonsyndrome.org	
420		Exhibit 7- 21 C.F.R. § 314.70	
421		Exhibit 8- Letter from Plaintiff's counsel enclosing documents for review	
422		Exhibit 9- Printouts from www.merck.com regarding Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis	
423		Exhibit 10-Printouts from www.fda.gov regarding COX-2 Selective (includes Bextra, Celebrex and Vioxx) and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	
424		Exhibit 11- Letter from Plaintiff's counsel enclosing documents for review	
425	1/3/10	Exhibit 12- Report of Findings dated 1/3/10	
426	3/29/10	Exhibit 13- Expert Report of Laura Bix dated 3/29/10	
427	4/4/2010	Exhibit 14- Expert Report of Laura Bix dated 4/4/10	
428		Exhibit 15- Article, "Examining the Conspicuousness and Prominence of Two Required Warnings on OTC Pain Relievers"	

Exh No.	Date	Description	Defendants' Objections
429		Exhibit 16- Defense Expert Report of Steven M. Weisman, Ph.D.	
430		Exhibit 17- Defense Expert Report of M. Laurentius Marais, Ph.D.	
431		Exhibit 18- Defense Expert Report of Margaret Fisher, M.D.	
432		Exhibit 19- Defense Expert Report of Elizabeth Rand, M.D.	
433		Exhibit 20- Defense Expert Report of Louis A. Morris, Ph.D.	
434		Exhibit 21- Defense Expert Report of Maja Mockenhaupt, M.D., Ph.D.	
435		Exhibit 22- Defense Expert Report of J. Paul Waymack, M.D., Sc.D.	
436		Exhibit 23- "Ibuprofen: An Analysis of Safety and Efficacy." (MC065017-MC065040)	
437	12/22/1993	Exhibit 24- 12/22/93-McNeil Consumer Products Company-Clinical Study Report- Phase IV- An Assessment of the Safety of Pediatric Ibuprofen (MC074066-MC074491)	
438		Exhibit 25- Citizen's Petition	
439		Exhibit 26- Petition for Reconsideration of Approval of New Drug Application (MC067236-MC067247)	
440		Exhibit 27- Article, "Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome: Does Early Withdraw of Causative Drugs Decrease the Risk of Death"	
441		Exhibit 28- Article, "Rare Adverse Reactions to Nonsteroidal Antiinflammatory Drugs"	
442		Exhibit 29- Article, "An Expanded Profile of Cutaneous Reactions to Nonsteroidal Anti-Inflammatory Drugs"	
443		Exhibit 30- Article, "Toxic Epidermal Necrolysis and Stevens Johnson Syndrome: Our Current Understanding"	
444		Exhibit 31- Article, "Changing the Status of Drugs from Prescription to Over-the-Counter Availability"	

Exh No.	Date	Description	Defendants' Objections
445		Exhibit 32- Article "The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Antiinflammatory Drugs: A Multinational Perspective"	
446		Exhibit 33- Case Report: "Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child."	
447		Exhibit 34- Case Report: "Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child."	
448	1991	Exhibit 35- 1991 PDR re Pediaprofen	
449	2002	Exhibit 36- 2002 Children's Motrin Box	
450		Exhibit 37- 21 C.F.R. 343	
451		Exhibit 38- 21 C.F.R. 201	
452		Exhibit 39- Handwritten notes of Laura Bix, Ph.D.	
453		Exhibit 40- Printouts from www.aami.org	
454	6/16/1995	Exhibit 41- 6/16/95 letter to Vivian Chester regarding final printed labeling (MC01A001479-MC01001487)	
455		Deposition of Lorraine Buchannan, R.N., M.S.N., C.R.R.N.	
456		Exhibit 1- Amended Notice of Deposition	
457		Exhibit 2- Internet Research on Stevens-Johnson Syndrome	
458		Exhibit 3- Case Report: "Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child."	
459		Exhibit 4- C.V. of Lorraine Buchannan	
460		Exhibit 5- Website for Independent Allied Health Consultants, Inc.	
461		Exhibit 6- C.V. of Carolyn Uveges	
462		Exhibit 7- Life Care Plan for Kiley Wolfe	
463		Exhibit 8- Medical records on disk	
464		Exhibit 9- Invoice for services	
465		Exhibit 10- Life Care Plan Worksheet	
466		Exhibit 11- Life Care Plan Worksheet	
467		Exhibit 12- Expert Report of Steven Pliskow, M.D.	
468		Exhibit 13- Life Table	
469		Exhibit 14- Notes from telephone call with Steven Pliskow, M.D.	

Exh No.	Date	Description	Defendants' Objections
470		Exhibit 15- Neuropsychological Evaluation Report of William Bruce Jones, Ph.D.	
471		Exhibit 16- Expert Report of William Bruce Jones, Ph.D.	
472		Exhibit 17- Notes from telephone call with Jonathan Walker, M.D.	
473		Exhibit 18- Expert Report of Philip Rosenthal, M.D.	
474		Exhibit 19- Internet research on Zofran and Phenergan	
475	2008	Exhibit 20- Milliman Research Report- 2008 U.S. organ and tissue transplant cost estimates and discussion	
476		Deposition of Royal Bunin, MBA	
477		Exhibit 1- Amended Notice of Deposition	
478		Exhibit 2- Letter from Bunin Associates to Messa & Associates dated April 12, 2010	
479		Exhibit 3- C.V. of Royal Bunin	
480		Exhibit 4- Printouts from Bunin Associates, P.C.	
481		Exhibit 5- Invoice for services	
482		Exhibit 6- Actuarial Economic Report (unsigned)	
483		Exhibit 7- Actuarial Economic Report (signed)	
484		Exhibit 8- Handwritten Note of Royal Bunin	
485		Exhibit 9- Social Security Administration Notice of Decision	
486		Exhibit 10- Life Care Plan for Kiley Wolfe	
487		Exhibit 11-Neuropsychological Evaluation Report and Expert Report of William Bruce Jones, Ph.D.	
488		Deposition of Talal Chatila, M.D.	
489		Exhibit 1- Notice of Deposition	
490		Exhibit 2- C.V. of Talal Chatila, M.D.	
491		Exhibit 3- Excerpts from Children's Hospital Boston medical records	
492		Exhibit 4- Medical Records	
493		Exhibit 5- Expert Report of Talal Chatila, M.D.	
494		Exhibit 6- CD of medical records reviewed	
495		Exhibit 7- Updated C.V. of Talal Chatila, M.D.	
496		Deposition of James B. Hoyme, M.D.	
497		Exhibit 1- Amended Notice of Deposition	
498		Exhibit 2- MMPI-2 Basic Service Report	
499		Exhibit 3- Invoice for services	
500		Exhibit 4- Fee Schedule	

Exh No.	Date	Description	Defendants' Objections
501		Exhibit 5- Expert Report of James B. Hoyme, M.D.	
502		Exhibit 6- Records from University Neurology	
503		Exhibit 7- Records from Steven Zuckerman, M.D.	
504		Exhibit 8- Records from Owen Scott, Ph.D.	
505		Exhibit 9- C.V. of James Hoyme, M.D.	
506	3/10/2010	Exhibit 10- Neuropsychological Evaluation performed March 10, 2010 and Expert Report of William Bruce Jones, M.D.	
507		Exhibit 11- Report and C.V. of Jonathan Walker, M.D.	
508		Exhibit 12- Plaintiff's Complaint	
500	No Date	The Report of Randall L. Tackett, Ph.D. as produced and relied on in the Maya v. J&J, Phila Co.	
502a	No Date	Randall L. Tackett, Ph.D. Curriculum Vitae	
502b	No Date	Randall L. Tackett, Ph.D. Case List/Testimonies	
502.1	No date	Index of 17 Publications that TEN is Solely Caused By Drugs Literature (also Ex674)	
502.2	No Date	Index of 57 Publications or Articles entitled SCIENTIFIC LITERATURE ON THE RELATIONSHIP OF IBUPROFEN TO SJS AND TEN (also Ex700.2)	
503	2005	Citizen Petition to Request Risk Assessment of SJS and Ten dated Feb 15, 2005	
503.1	2/15/2005	Letter from FDA to Dr. Salisbury and petitioners confirming receipt of Citizen's Petition on 2/15/2005 and docketing the Petition for adding SJS warnings.	
503.2	2/24/2005	Letter to Dr. Lester Crawford and copied to Dr. Steve Galson and Congressional members urgin quick action on SJS and TEN warnings for ibuprofen products.	
503.4	4/7/2005	U.S. FDA Press Release on changing OTC NSAID products for serious skin reactions/withdrawal of Bextra	
503.5	4/7/2005	U.S. FDA Public Health Advisory concerning labeling changes and skin reactions.	
503.6	4/7/2005	Website printout of FDA actions regarding chronology COX-II and non-selective NSAIDS showing that labeling templates didn't come out until 6/15/2005	

Exh No.	Date	Description	Defendants' Objections
503.7	7/12/2005	Supplemental Letter to McNeil regarding CBE labeling request for OTC products incorporating and adding additional information to labeling after meetings between FDA and industry	
504	No Date	FDA Question and Answers on Regulatory Actions for the COX-2 Selective and Non-Selective Non-Steroidal Anti-inflammatory drugs (NSAIDs)	
505	2005	FDA Food & Drug Administration - -FDA News - - "FDA Announces Series of Changes to the Class of Marketed Non-Steroidal Anti-inflammatory Drugs (NSAIDs) dated April 7, 2005	
506	No Date	Department of Health & Human Services NDA Labeling Revision Request	
507	2006	Citizen's Petition FDA Response letter to Dr. Roger Salisbury Docket No. 2005P-0072/CP 1 dated June 22, 2006 & Outline of items the FDA did not reject	
508	1998	Moore, Thomas J., et. al, "Time to Act on Drug Safety", JAMA, Vol. 279, No. 19, pages 1571-1573, (1998)	
509	1998	Lazarous, Jason, et. ai, "Incidence of Adverse Drug Reactions in Hospitalized Patients", JAMA, Vol. 279 No. 15, pages 1200-1205, (1998)	
510	2006	Furberg, Curt D." et. al, "The FDA and Drug Safety: A Proposal for Sweeping Changes", Archives of Internal Medicine, Alliance for Human Research Protection (2006).	
511	No Date	Title 21 - - Food and Drugs, Chapter 1 - - Food and Drug Administration Department of Health and Human Services, SubChapter D – Drugs for Human Use, Part 314	
512	2001	Ioannidis, John P. M.D., et. al, "Completeness of Safety Reporting in Randomized Trials", JAMA, Vol. 285, No.4, pages 437 - 443, (2001)	

Exh No.	Date	Description	Defendants' Objections
513.1-513.5	2005	1) Memorandon From Paul Andreason, MD to File, Recommendation of Approvable Action for [Provigil] for the Treatment of ADHD dated October 12, 2005, 2) Memorandum, FDA Medical Officer review of Provigil, February 27, 2006, 3) Psychopharmacologic Advisory Committee (PDAC) March 23, 2006; 4) June 28, 2007, Memorandum from Charlene Flowers of FDA to Lisa Matthis, MD re 1-year Post-Pediatric Exclusivity Postmarketing ADE Review; and 5) November 28, 2007, FDA Powerpoint Entitled "Provigil One Year Post Exclusivity Adverse Event Review"	
514	2002	Lasser, M.D. Karen E., et. al, "Timing of New Black Box Warnings and Withdrawals for Prescription Medications", JAMA, Vol. 287, No. 17, pages 2215 - 2220, (2002)	
515	2005	Bennett, M.D., Charles. 1., et. al, "The Research on Adverse Drug Events and Reports (RADAR) Project", JAMA, Vol. 293, No. 17, pages 2131-2140; Letters 1206 - 1107, (2005)	
516	2002	Psaty, M.D., Bruce M., et. al., "Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions", JAMA, Vol. 292, No. 21, pages 2622 - - 2646, (2004); Strom, M.D. Brian 1., "Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions", JAMA, Vol. 292, No, 21, pages 2643 - 2646, (2004); Omar, M A, et.al, "FDA adverse event reports on statin-associated rhabdomyolysis", The Annals of Pharmacotherapy, Vol. 36, No.2, pages 288-295, (2002)	
517	1999	Scott, H. D., et. al., "Physician reporting of adverse drug reactions. Results of the Rhode Island Adverse Drug Reaction Reporting Project", JAMA, Vol. 263, No. 13, (1990); Brewer, M.D., Timothy, et. al, "Postmarketing Surveillance and Adverse Drug Reactions", JAMA, Vol. 281, No.9, pages 281:824c829,(1999)	

Exh No.	Date	Description	Defendants' Objections
518	2004	Mittmann, Nicole, et. al, "Evaluation of the Extent of Under-Reporting of Serious Adverse Drug Reactions", Drug Safety, 27 (7),477 -487, (2004) in Canada 1 in 25 to 1 in 10	
519	2003	Title 21- Food and Drugs Chapter 1-Food and Dmg Administration, Department of Health and Human Services, SubChapter D - Drugs for Human Use, Part 314.80, pages 121-127, (2003)	
520	1992	57 Federal Register 61437, FDA Guideline for Postmarketing Reporting of Adverse Tab 20 Drug Experiences, Docket No. 85D-0249, December 24, 1992	
521	1997	FDA Guidance For Industry; Postmarketing Adverse Experience Reporting for Human Dmg and Licensed Biologic Products: Clarification of What to Report, August 1997	
522	2001	FDA Guidance For Industry: Postmarketing Safety Reporting for Human Dmg and Biological Products Including Vaccines, March 2001	
523	1989	Stern, M.D., Robert S., et. al, "Usefulness of case report literature in determining drugs responsible for toxic epidermal necrolysis", J Am Acad Dermatol, 21:317-22, (1989)	
524	No Date	McNeil's Failure to File/Report Scientific Literature in NDAs and Postmarketing reports for Motrin Products;	
525	No Date	2 SJS Cases Which are the subject of the Failure to Report SJS and the Failure to Report SJS cases to Final BUFS Study Report, FDA Medical Officer, and U.S. Non-Prescription Drug Advisory Committee (NDAC)	
526		McNeil Memorandum RE: IBUPROFEN NDA PROJECT, dated January 11, 1984, MC064778	
527	1984	McNeil PETITION FOR RECONSIDERATION NDA 19-012 & NDA 18-989 dated June 18, 1984.	

Exh No.	Date	Description	Defendants' Objections
528	1984	McNeil PETITION FOR RECONSIDERATION NDA 19-012 & NDA 19-989 dated June 18, 1984 MC067238 & FDC Reports 46(13): T&C-I (March 26) 1984, Trade & Govt. Memos OTC Ibuprofen Labeling based on Rx Package insert information	
529	1984	McNeil Memorandum to Robert Temple, M.D., RE: Ibuprofen- Summary Basis of Approval, dated May 31, 1984	
530	No Date	Petition for Reconsideration by McNeil Risk of Death higher for Ibuprofen	
531	1985	McNeil Memorandum Subject: National Kidney Foundation dated May 23, 1985	
532	1983	Judith Jones, M.D. Arthritis Advisory Committee Meeting Handouts, dated September 14, 1983	
533	1984	Bellevue Hospital Center Letter to Anthony R. Temple, best updating on ibuprofen from Lewis Goldfrank, dated September 12, 1984	
534	1983	Korberly Report: Ibuprofen Review prepared for: David E. Collins by Marsha M. Silberstein, M.D., Barbara H. Korberly, Pharm D. dated August 12, 1983	
535	1988	Mc Neil Letter to FDA regarding New Drug Application Ibuprofen Pediatric Suspension 80mg 15ml, dated March 31, 1988	
536	No Date	Ibuprofen Pediatric Suspension, 80mg / 5ml New Drug Application, Overview of Sponsored Studies, NDA 19-842, MCO6A 000878	
536.1	2/7/1992	Section 6.0 of Study 89-945, pg. 39, MC063225- Case report of vesiculobullous reaction in child exposed to Children's Motrin in clinical trial.	
536.2	19-Jul-99	McNeil Memo by Laura Reel to Kim McKonly-- Summary of Adverse events involving bullous reactions in McNeil's trials	
537	No Date	NDA 19-842 Summary Basis of Approval	
538	No Date	Ibuprofen Pediatric Suspension, 80mg / 5ml New Drug Application, Other Studies and Information, MC06A 000908	
539	No Date	Graph of SRS 1980 Through 1989 17 years or younger, Motrin, Advil, Rufen, Ibuprofen Nuprin	

Exh No.	Date	Description	Defendants' Objections
540	1990	McNeil Letter Subject: Minutes of Industry Meeting with FDA Post Marketing Surveillance Program - Ibuprofen suspension, dated January 29, 1990 .	
541	1996	Mitchell, Allen A., et. al., "When a Randomised Controlled Trial is Needed to Assess Drug Safety", Drug Safety, 13(1): 125-24, (1996)	
542	1993	BUFS - - Draft Final Report, dated November 2, 1993	
543	1992	NDA 19-842 Pedia-Profen Ibuprofen Suspension Request for FDA Meeting dated 6/11/92, Regulatory Copy	
544	1993	Medical Officer Review, NDA 20-516 (Supplement to NDA 19-842), dated December 22,1993, pages 1 -29.	
545	No Date	BUFS Total cases hospitalized with cutaneous and mucocutaneous	
546	No Date	Boston Fever	
546.1	1991-1993	Mucocutaneous/Cutaneous reactions requiring outpatient physician office visits in BUFS-A00000007-A00002344;B00000021-B00002267;C00000262-C0001686	
546.2	1991-1993	Electronic DataSet and electronic files for BUFS produced in Langstaff	
547	2005	Frequency of SJS Docket Number 2005P-0072/CP1 page 3	
548	No Date	Presentation to the Arthritis and Non-Prescription Drugs Advisory Committees on the switch of Children's Motrin Ibuprofen Suspension from Prescription to nonprescription status, pages 1 – 269.	
548.1		Medical Officer's Review of Children's Motrin Rx. To OTC switch with tables	
549	No Date	Presentation to the Arthritis and Non-Prescription Drugs Advisory Committees on the switch of Children's Motrin Ibuprofen Suspension from Prescription to nonprescription status, pages 270	
550	No Date	FD-356H New Drug Application for Coated Compressed Tablets 'Motrin(ibu, U-18,53), Vol 1.1, Part 1 & 2	

Exh No.	Date	Description	Defendants' Objections
551	1994	Department of Health, Education and Welfare, Public Health Service NDA 17-463, September 19, 194, To: Schumann, PhD, From: J. Richard Crout, MD	
552	No Date	Motrin 17-463, Three Month Update, LFROO101478, Vol. I	
553	1976	NDA 17-463, Motrin Tablets, (ibu) BI - annual report, September 10, 1976, LFR00107593, Vol. 1.1	
554	No Date	NDA 17-463, Three Month Update, LFR00101939, Vol. II	
555	1974	NDA 17-463 Side Effects and Dose Level for Motrin Protocol 012 173, 8/8/74	
556	No Date	NDA 17-463, Motrin Update, LFR00102924, Vol. IV	
557	No Date	Motrin Osteoarthritis Study- Table 41 Protocol 320, LFR00103190	
558	No Date	C 14-171, Upjohn, Initial Clinical Report - Rheumatoid Arthritis	
559	No Date	C27-136, Adverse Reactions and concomitant Therapy, LFR 00025190	
560	No Date	C15-64, Upjohn, Initial Clinical Report - Rheumatoid Arthritis LFR 00019750	
561	No Date	Motrin (ibu, U-18,573), NDA 17-463, First Quarterly Update Drug Experience Reports, FD-1639	
562	1976	Motrin Tablets, NDA 17-463, (ibu) Bi-Annual Report, September 10, 1976, Vol. II	
563	1985	NDA 19-012, Nuprin Tablets Adverse Reactions, ADR's from Clinical Trials in Elderly Patients, January 29, 1985, Vol. 27	
564	1976	NDA 17-463, Motrin Tablets (ibu) Bi-Annual Report, March 2, 1976 Vol. IV .	
565	No Date	Department of Health, Education, and Welfare, Public Health Service, To: Dr. Schumann, From J. Richard Crout, M.D. LFR00149316	
566	No Date	Motrin, NDA 17-463, LFR00121007, Reaction, Erythema Multiform	
567	1981	Motrin Tablets, NDA 17-463, (ibu) Progress Report, Vol. 6 – Adverse Reactions, September 30, 1981, LFR00125727	
568	No Date	Motrin Tablets, NDA 17-463, Reaction Stevens Johnson Syndrome LFR00126730	

Exh No.	Date	Description	Defendants' Objections
569	1992	<i>Index of FDA 1639s</i> Being Submitted for the Time Period 07/01/1991 Through 07/20/1992, Motrin Tablets NDA 17-463	
570.1-57-.50	2005	Package Inserts Children's Motrin Rx, PDR 1994 - 2005	
570.1	1988	Proposed Labeling for Pediaprofen filed with NDA 19-842	
570.2	1989	FDA approved labeling for Pediaprofen-1989	
570.3	1990	Approved Labeling for Pediaprofen w/ any labeling changes-1990	
570.4	1991	Approved Labeling for Pediaprofen w/ any labeling changes-1991	
570.5	1992	Approved Labeling for Pediaprofen w/ any labeling changes-1992	
570.6	1993	Approved Labeling for Pediaprofen w/ any labeling changes-1993	
570.7	1994	Approved Labeling for Pediaprofen w/ any labeling changes-1994	
570.8	1995	Approved Labeling for Pediaprofen w/ any labeling changes-1995	
570.9	1996	Approved Labeling for Rx. Children's Motrin w/ any labeling changes-1996	
570.10	1997	Approved Labeling for Rx. Children's Motrin w/ any labeling changes-1997	
570.11	1998	Approved Labeling for Rx. Children's Motrin w/ any labeling changes-1998	
570.12	1999	Approved Labeling for Rx. Children's Motrin w/ any labeling changes-1999	
570.13	2000	Approved Labeling for Rx. Children's Motrin w/ any labeling changes-2000	
570.14	2001	Approved Labeling for Rx. Children's Motrin w/ any labeling changes-2001	
570.15	2002	Approved Labeling for Rx. Children's Motrin w/ any labeling changes-2002	
570.16	2003	Approved Labeling for Rx. Children's Motrin w/ any labeling changes-2003	
570.17	2004	Approved Labeling for Rx. Children's Motrin w/ any labeling changes-2004	
570.18	2005	Approved Labeling for Rx. Children's Motrin w/ any labeling changes-2005	
570.19	2006-2007	Approved Labeling for Children's Motrin in 2006-2007	

Exh No.	Date	Description	Defendants' Objections
570.20	1995-2004	CBE labeling changes submitted by McNeil for Adult and Children's Motrin via 314.70 LFR01290746-LFR01295758	
570.21	1995	Children's Motrin label	
570.22	1996	Children's Motrin label	
570.23	1997	Children's Motrin label	
570.24	1998	Children's Motrin label	
570.25	1999	Children's Motrin label	
570.26	2000	Children's Motrin label	
570.27	2001	Children's Motrin label	
570.28	2002	Children's Motrin label	
570.29	2003	Children's Motrin label	
570.30	2004	Children's Motrin label	
570.31	2005	Children's Motrin label	
570.32	2006	Children's Motrin label	
570.33	2007	Children's Motrin label	
570.34	2008	Children's Motrin label	
570.35	2009	Children's Motrin label	
570.36	2010	Children's Motrin label	
570.37	2011	Children's Motrin label	
571	No Date	21 CFR 201.57, Federal Regulations, The Federal Register	
572	No Date	21 CFR 314.70, Federal Regulations, The Federal Register	
573	1999	Waller, P. <u>Pharmacoepidemiology and Drug Safety</u> , "Responding to Drug Safety Issues", 8: 535-552, (1999)	
574	1999	Sheridan, R.L., et. al., J Bum Care Rehabil, "Management of Severe Toxic Epidermal Necrolysis in Children", 20:497-500, (1999)	
575	2004	PDR 2000, Physician's Desk Reference, Zithromax, Pfizer Inc. /2389 Bextra, November 2004, LAB-0266-4.0	
576	1999	Federal Register, Part II Department of Health and Human Services 21 CFR, Part 201, et al., March 17, 1999	
577	2003	Mockenhaupt, M., et al., The Journal of Rheumatology, "The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated With Nonsteroidal Antiinflammatory Drugs: A Multinational Perspective," Vol. 30:10, pp. 2234-2240 (2003).	

Exh No.	Date	Description	Defendants' Objections
578	No Date	Foreign Labeling, Dolormin for Children	Lacks authentication (Rule 901)
579	1982	Rx. Adult Motrin package insert-1982	
579.1	1983	Rx. Adult Motrin package insert-1983	
579.2	1984	Rx. Adult Motrin package insert-1984	
579.3	1985	Rx. Adult Motrin package insert-1985	
579.4	1986	Rx. Adult Motrin package insert-1986	
579.5	1987	Rx. Adult Motrin package insert-1987	
579.6	1988	Rx. Adult Motrin package insert-1988	
579.7	1989	Rx. Adult Motrin package insert-1989	
579.8	1990	Rx. Adult Motrin package insert-1990	
579.9	1991	Rx. Adult Motrin package insert-1991	
579.1	1992	Rx. Adult Motrin package insert-1992	
579.11	1993	Rx. Adult Motrin package insert-1993	
579.12	1994	Rx. Adult Motrin package insert-1994	
579.13	1995	Rx. Adult Motrin package insert-1995	
579.14	1996	Rx. Adult Motrin package insert-1996	
579.15	1997	Rx. Adult Motrin package insert-1997	
579.16	1998	Rx. Adult Motrin package insert-1998	
579.17	1999	Rx. Adult Motrin package insert-1999	
579.18	2000	Rx. Adult Motrin package insert-2000	
579.2	2001	Rx. Adult Motrin package insert-2001	
579.21	2002	Rx. Adult Motrin package insert-2002	
579.22	2003	Rx. Adult Motrin package insert-2003	
579.23	2004	Rx. Adult Motrin package insert-2004	
579.24	2005	Rx. Adult Motrin package insert-2005	
579.25	2006	Rx. Adult Motrin package insert-2006	
580	No Date	Package Insert Adult Motrin OTC	
580.1	1983	Adult Motrin OTC label-1983	
580.2	1984	Adult Motrin OTC label-1984	
580.3	1985	Adult Motrin OTC label-1985	
580.4	1986	Adult Motrin OTC label-1986	
580.5	1987	Adult Motrin OTC label-1987	
580.6	1988	Adult Motrin OTC label-1988	
580.7	1989	Adult Motrin OTC label-1989	
580.8	1990	Adult Motrin OTC label-1990	
580.9	1991	Adult Motrin OTC label-1991	
580.1	1992	Adult Motrin OTC label-1992	
580.11	1993	Adult Motrin OTC label-1993	
580.12	1994	Adult Motrin OTC label-1994	
580.13	1995	Adult Motrin OTC label-1995	
580.14	1996	Adult Motrin OTC label-1996	
580.15	1997	Adult Motrin OTC label-1997	

Exh No.	Date	Description	Defendants' Objections
580.16	1998	Adult Motrin OTC label-1998	
580.17	1999	Adult Motrin OTC label-1999	
580.18	2000	Adult Motrin OTC label-2000	
580.19	2001	Adult Motrin OTC label-2001	
580.20	2002	Adult Motrin OTC label-2002	
580.21	2003	Adult Motrin OTC label-2003	
580.22	2004	Adult Motrin OTC label-2004	
580.23	2005	Adult Motrin OTC label-2005	
580.24	2006	Adult Motrin OTC label-2006	
582	1985	Bigby, M., et al., J Am Acad Dermatol, "Cutaneous reactions to Nonsteroidal anti inflammatory drugs", 12:866-876 (1985)	
583	1984	Stern, R., et al., JAMA, "An Expanded Profile of Cutaneous Reactions To Nonsteroidal Anti-inflammatory Drugs", 252:1433-1437, (1984) MacKie, Rona,	
584	1996	Ibuprofen (Adult) 1978 - - 1989 Ibuprofen (Adult) 1990 - -1996 Ibuprofen (Adult) 1997 - 2002 NAIDS / Ibuprofen Pediatrics	
584	1978-2005	Citizen Petition Literature submitted on 2/15/2005 via citation in Tables 1-5	
590.1	5/19/04	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 5/19/04	
590.2	5/20/04	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 5/20/04	
590.3	7/25/07	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 7/25/07	
590.4	10/26/07	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 10/26/07	
590.5	11/13/07	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 11/13/07	
590.6	12/4/07	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 12/4/07	
590.7	12/5/07	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 12/5/07	
590.8	12/11/07	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 12/11/07	
590.9	2/20/08	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 2/20/08	
590.10	5/20/08	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 5/20/08	
590.11	6/24/08	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 6/24/08	

Exh No.	Date	Description	Defendants' Objections
590.12	6/26/08	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 6/26/08	
590.13	6/27/08	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 6/27/08	
590.14	6/30/08	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 6/30/08	
590.15	10/2/08	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 10/2/08	
591	5/13/2004	Oral deposition and accompanying exhibits of Edward Nelson, M.D., 5/13/04	
592.1	5/11/2004	Oral deposition and accompanying exhibits of Vivian Chester, 5/11/04	
592.2	8/9/2007	Oral deposition and accompanying exhibits of Vivian Chester, 8/9/07	
593	4/14/2004	Oral deposition and accompanying exhibits of Eileen Helzner	
594.1	5/11/2004	Oral deposition and accompanying exhibits of Tizianna Fox, 5/11/04	
594.2	11/20/2007	Oral deposition and accompanying exhibits of Tizianna Fox, 11/20/07	
595.1	5/12/2004	Oral deposition and accompanying exhibits of Willie Pagsuyuin, 5/12/04	
595.2	9/7/2007	Oral deposition and accompanying exhibits of Willie Pagsuyuin, 9/7/07	
595.3	5/14/2008	Oral deposition and accompanying exhibits of Willie Pagsuyuin, 5/14/08	
597.1	6/20/2007	Oral deposition and accompanying exhibits of Mary Joan Denisco, Pharm.D., 6/20/07	
597.2	11/21/2007	Oral deposition and accompanying exhibits of Mary Joan Denisco, Pharm.D., 11/21/07	
597.3	12/22/1993	12.22.1993 Dr. Widmark's FDA Review of BUFS. (See MC063457-MC063485 (Ex 4 to the depo.)	
597.4	1999	Denisco Exhibit #9 taken on 4/07/2004-Letter from Drs. Lesko/Mitchell regarding 1991 ADRs from BUFS, including cases of hospitalized EM, 3 cases of outpatient EM, 1 case of outpatient vesiculobullous rash	
598	4/28/2004	Oral deposition and accompanying exhibits of Paula Oliver, 4/28/04	
599	4/28/2004	Oral deposition and accompanying exhibits of Peter Bell, 4/28/04	

Exh No.	Date	Description	Defendants' Objections
600	5/19/2004	Oral deposition and accompanying exhibits of Brenda Bass, 5/19/04	
601.1	5/19/2004	Oral deposition and accompanying exhibits of Ashley McEvoy, 5/19/04	
601.2	4/1/2009	Oral deposition and accompanying exhibits of Ashley McEvoy, 4/1/09	
602.1	5/20/2004	Oral deposition and accompanying exhibits of Bob Christiansen, 5/20/04	
602.2	12/2/2008	Oral deposition and accompanying exhibits of Bob Christiansen, 12/2/08	
602.3	6/15/2004	Oral deposition and accompanying exhibits of Cathy Gelotte; 6/15/04	
602.4	10/20/2010	Oral deposition and accompanying exhibits of Cathy Gelotte; 10/20/10	
603	2009	GAO – Report to the Congress – High Risk Series An Update (2009)	Lacks authentication (Rule 901)
605	2009	U.S. Supreme Court – Wyeth, Petitioner vs Diana Levine No. 06-1249 (2009)	
606	2009	Department of Health and Human Services, Food and Drug Administration Office of Device Evaluation, Letter to President Barack H. Obama, Exhibit A1, pp 1- 6, April 2, (2009)	Lacks authentication (Rule 901)
607	2008	Testimony of Catherine E. Woteki, Ph.D., R.D. Science and Mission at Risk:FDA's Self Assessment Subcommittee on Oversight and Investigations Committeeon Energy and Commerce, (2008)	Lacks authentication (Rule 901)
608	No Date	Statement of Dale Nordenberg, M.D. before the U.S. Congress Committee on Energy and Commerce, Subcommittee on Oversight and Investigations,	Lacks authentication (Rule 901)
609.1 & 609.2	2008	Testimony of Gail H. Cassell, Ph.D, before the Subcommittee on Oversightand Investigations of the Committee on Energy and Commerce House ofRepresentatives on Science and Mission at Risk: FDA's Self Assessment, (2008) 609.2 is from the Congressional Record	Lacks authentication (Rule 901)
610	2008	Testimony Former Commissioner United States Food and Drug AdministrationBefore The House Committee on Oversight and Government Reform, Hearing On:Should FDA Drug and Medical Device Regulation Bar State Liability Claims?,(2008)	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
611	2008	Testimony House Committee on Oversight and Investigations Preemption --Drug and Medical Devices (2008)	Lacks authentication (Rule 901)
612	2007	FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology, (2007)	
613	2007	GAO Testimony Before the Subcommittee and Health, Committee on Energyand Commerce, House of Representatives, -- Drug Safety Further Actions Neededto Improve FDA's Postmarket Decision – Making Process, (May 9, 2007)	Lacks authentication (Rule 901)
613.1	2005	Testimony of Dr. Sandra Kweder, Deputy Director, OND, FDA, US Dept of Health & Human Svcs, 3/1/05 before the Committee on Health, Education, Labor & Pensions U.S. Senate	Lacks authentication (Rule 901)
613.2	2005	Video excerpt of the testimony of Dr. Sandra Kweder, Deputy Director, OND, FDA, US Dept of Health & Human Svcs, 3/1/05 before the Committee on Health, Education, Labor & Pensions U.S. Senate	Lacks authentication (Rule 901)
614	2007	FDA Science and Mission at Risk – Synopsis of A Report of the Food and Drug Administration's Science Board (2007)	
615	2003	Department of Health and Human Services, Office Of Inspector General-- FDA's Review Process for New Drug Applications – A Management Review(2003)	
616	2000	GAO – Testimony – Adverse Drug Events – Substantial Problem but MagnitudeUncertain, Statement of Janet Heinrich, Associate Director, Health Financing andPublic Health Issues, Health and Human Services Division, GAO/T-HEHS-00-53,pp 1 – 12, (2000)	Lacks authentication (Rule 901)
617	1992	GAO – Report to the Chairman, Subcommittee on Regulation Business Opportunitiesand Energy, Committee on Small Business House of Representatives – Non-Prescription Drugs – Over the Counter and Underemphasized, GAO/PEMD-92-9,(1992)	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
618	1992	GAO – Testimony Before the Subcommittee on Regulations, Business Opportunities and Energy Committee on Small Business House of Representatives, Overthe Counter Drugs, Gaps and Potential Vulnerabilities in the Regulatory System,GAO/T-PEMD-92-8, (1992)	Lacks authentication (Rule 901)
619	1992	GAO –Testimony Before the Subcommittee on Human Resources and Inter-government Relations Committee on Government Operations House of-Representatives – Nonprescription Drugs – Over the Counter and UnderemphasizedStatement of Kwai-Cheung Chan, GAO/T=PEDMID-92-5, (1992)	Lacks authentication (Rule 901)
619.1	1982	GAO – Report To The Secretary of Health and Human Services – FDA Can Further Improve Its Adverse Drug Reaction Reporting System, (1982)	Lacks authentication (Rule 901)
620.1		McNeil/J&J SCAR Reports for Motrin Products, 1995-2005, Volume I	Lacks authentication (Rule 901)
620.2		McNeil/J&J SCAR Reports for Motrin Products, 1995-2005, Volume II	Lacks authentication (Rule 901)
620.3		McNeil/J&J SCAR Reports for Motrin Products, 1995-2005, Volume III	Lacks authentication (Rule 901)
621-621.20	No Date	McNeil's/PNU's spontaneous reports for other single ingredient ibuprofen products between 1973-1997	Lacks authentication (Rule 901)
622-622.30	No Date	McNeil's \ PNU's Spontaneous Reports for other single ingredient ibuprofen products 1973 and 1997	Lacks authentication (Rule 901)
623	1996	Comprehensive Review of the Safety of Ibuprofen in Pediatric Patients written by Kirstner for Michael Hoehn	
624	2006	GAO, Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process 5 (GAO-06-402, 2006), http://www.gao.gov/new.items/d06402.pdf .	Lacks authentication (Rule 901)
625a	7/28/1993	Thomas N. Gates memo to Chilsea & Collins MC 68111	
625.4	7/15/1986	Final Printed Label for the marketing of Ibuprofen OTC NDA 19-012-Nuprin PIL	
625.5	2/16/2005	Data Qualification Plan, PV SCEPTRE Transition, Version 1.0, Sandy Schoenwald, MOT00013181-13207	

Exh No.	Date	Description	Defendants' Objections
625.6	10/12/2004	Email from Michelle Jennelle to Steven Silber on PV-BRM and McNeil with attachments	
625.7	11/14/2005	Email from Sandra Schoenwald to Steven Silber, M.D. PV function with attachments	
625.8	11/23/2005	Email from Sandra Schoenwald to Steven Silber, M.D.-Safety Review Committee-with attachments	
625.9	2/23/2006	Email from Sandra Schoenwald to Steven Silber, M.D.-Safety Review Committee-with attachments-SRC	
625.1	1989	FDA Medical Officer Review of NDA 19-842 with attachments, Admitted into evidence in S. Johnson as Ex.#2294	
625.11	1994	FDA correspondence/McNeil and rejects SNDA for pain indication for Children's Motrin	
625.12	6/22/1994	Children's Motrin Suspension OTC Switch & Pain Indication: The FDA advised us that they do not have the resources to review the OTC switch application at present and requested that we withdraw this supplement. We indicated to the agency that this OTC switch represents a top priority for McNeil and that its timing is critical for Hatch/Waxman exclusivity and competitive reasons in general.	
625.13	no date	FDA Medical Officer Review of NDA 20-516-Statistical Review, MC05A002136-2139	
625.14	4/6/2004	Email from Steven Silber to Jo Ellen Schweinle	
625.15	10/21/2005	Email from Michelle Rubincam to Caroline Densmore	
625.16	4/30/2004	Email from Chuck Norsigian to Steven Silber re: PV	
625.17	no date	McNeil PV training Power Point presentation slides	
625.18	No date	McNeil Queries for EM, SJS and TEN from their clinical trial databases, MOT00000606-614	
625.19	2/8/2004	Email from Steven Silber to Kenneth Kwong, M.D. FDA Inspection- AE reporting	
625.2	11/3/2003	Email from Steven Silber to Kenneth Kwong, M.D. FDA Inspection- AE reporting	
625.21	7/21/2004	Email from Kenneth Kwong to Steven Silber regarding PV issues	
625.22	5/9/1995	DDMAC letter regarding CM	

Exh No.	Date	Description	Defendants' Objections
625.23	14-Jun	DDMAC letter regarding CM	
625.24	28-Jul-83	McNeil Memo Rx. To OTC Switch of Ibuprofen	
625.25	2/11/2005	Email from Jeffrey Leebaw to Tony Temple regarding SJS standby statement	
625.26	2/14/2005	Email from Dr. Temple to Wayne Snodgrass, M.D.	
625.27	2/23/2005	Email from Emilia Lonardo to Dr. Temple about getting copies of Citizen's Petition for SJS warnings	
625.28	3/2/2005	Email from Kathy Fallon to group regarding SJS story and quote of Fallon	
625.29	3/15/2005	Email from Beth Gadney to group regarding SJS lawsuit	
625.3	3/14/2005	Email from Lois Clymer to group regarding Flag 3 S SJS updated with attachments	
625.31	3/7/2005	Email from Lois Clymer to group regarding Flag 3 S SJS updated with attachments	
625.32	4/4/2005	Email from Lois Clymer to group regarding Flag 3 S SJS updated with attachments	
625.33	3/21/2003	Email regarding newstory about another SJS lawsuit	
625.34	3/26/2003	Email from Dr. Temple to Hiral Mankad regarding Standby Statement about SJS	
625.35	4/21/2003	Email from Dr. Temple to Helen Hohman regarding Ovid literature search for SJS and TEN and ibuprofen	
625.36	10/3/2003	Email from Dr. Temple to John Kim regarding Motrin story and action plan	
625.37	8/17/2005	Risk MAP review Motrin IB and SJS	Lacks authentication (Rule 901)
625.38	8/5/2005	FDA letter to Salisbury regarding Citizen's Petition SJS warnings in McNeil's files, MOT00000951	
625.39	7/8/2005	Email from Doug Bierer to group re Crawford meeting and OTC labeling changes after 6/15/2005 announcement with attachments	
625.4	2005-2006	Various Advertising and Promotional forms and documents discussing new labeling changes-media initiative to draw attention to safety of Tylenol	Lacks authentication (Rule 901)
625.41	Jul-05	Copy Label Approval of Motrin labels for new SJS warnings	

Exh No.	Date	Description	Defendants' Objections
625.42	Oct-05	Copy Label Approval of Motrin labels for new SJS warnings-Pediatric and Adult labels	
625.43		McNeil's response to FDA's Proposed labeling for OTC NSAID products	
625.44		market Research for Ibuprofen products with attachments	
625.45	10/29/2004	Email from Kenneth Kwong to Steven Silber regarding PV issues with attachment	
625.46	10/12/2004	Email from Michelle Janelle to Steven Silber regarding PV between BRM and McNeil	
625.47	6/21/2004	Power Point Presentation Slides by Larry Johnson, M.D. BRM/McNeil OTC Support projecgt	
625.48	5/20/2004	Email from Kwong to Silber regarding Compliant Vigilance MAP	
625.49	Jan-04	Agenda for meeting between BRM and MCSP with Power Point Slides	
625.5	8-Jun-09	J&J PRD, BRM Briefing Document on Ultracet	
625.51	2005-2006	SAEC Invoices and payments for SJS/TEN consortium	
625.52	1995-2005	Product Safety Review Committee and quarterly reports for AES for Motrin products and emails	
625.41	No Date	Final Printed Label for the marketing of Ibuprofen OTC NDA 18-989-Advil PIL (NDA Approved 5/18/84)	
626	2002	WHO ADE's for Ibuprofen 1982-1991 and 1992-2002	Lacks authentication (Rule 901)
626.1-626.4	1969-2004	McNeil's 2004 data extract from WHO produced in Langstaff with reports	Lacks authentication (Rule 901)
627	2003	The FDA spontaneous reports printouts (SRS and AERS) from 1969 - 2003 for single ingredient ibuprofen products	Lacks authentication (Rule 901)
627.1-4	1969-2005	U.S. FDA SRS/AERS electronic data of AERS reports for ibuprofen products and other drugs	Lacks authentication (Rule 901)
628	No Date	The BUFS clinical trial data base and all underlying documents including hospitalization records	Lacks authentication (Rule 901)
628.1		BUFS Final Study Report	
628.2	2/15/1991	BUFS Case I.D.# 0072-05 & 300021-positive rechallenge--SJS case and underlying case report forms and hospital records	Lacks authentication (Rule 901)
628.2	2/19/1992	BUFS Case I.D.# 38932166, Case #601-Staph scalded skin syndrome/EM	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
628.3	8/31/1991	BUFS Case I.D.#16911811, Case #555-EM	Lacks authentication (Rule 901)
628.4	11/24/1992	BUFS Case I.D.#:64052933, Case#2953-EM	Lacks authentication (Rule 901)
628.5	2/21/1992	BUFS Case I.D.#38331659, case#2564-dermatitis, conjunctivitis	Lacks authentication (Rule 901)
628.6	3/29/1993	BUFS Case I.D.#86597582, 4228-blistering lesion, dehydration, dry areas of skin	Lacks authentication (Rule 901)
628.7	2/24/1993	BUFS Case I.D.#78869346, Case#4234-dehydration, scattered rash on face, cheeks, arms-	Lacks authentication (Rule 901)
628.8	4/20/1991	BUFS Case I.D.#6803929, Case#581-rash over her trunk, dry cracked lips, moderate dehydration-6%	Lacks authentication (Rule 901)
628.9	10/4/1991	BUFS Case I.D.#20414459, Case # 1388-red papular splotchy rash in diaper area and back, some are pea size and some are larger, rash spreading to extremities. Toxic erythema-delayed drug reaction	Lacks authentication (Rule 901)
628.1	4/26/1991	BUFS Case I.D.#550282F, Case#751--stomatitis-blister in her mouth, dehydration, fever, mucositis	Lacks authentication (Rule 901)
628.11	2/17/1993	BUFS Case I.D.#77568159-macular rash to extremities and groin, and mouth pain; pharyngitis, cervical lymphadenopathy, . Was no other medications except fever study medication.	Lacks authentication (Rule 901)
628.12	6/29/1992	BUFS Case I.D.#52643849, Case #2967-dehydration, pharyngitis, facial swelling, lesions in mouth-stomatitis, rash-raised lesions with central pallor, some are pustular.	Lacks authentication (Rule 901)
628.13	7/30/1992	BUFS Case I.D.#55445880, case # 2933-vesicles on tongue, mucositis, stomatitis, cervical adenopathy, dehydration	Lacks authentication (Rule 901)
628.14	1/26/1993	BUFS Case I.D.#72162218, Case# 3576-exanthem, allergic reaction, dehydration,	Lacks authentication (Rule 901)
628.15	7/20/1992	BUFS Case I.D.#54645311, Case# 2800-erythematous macular rash on chest, back spreading down arms and legs;	Lacks authentication (Rule 901)
628.16	3/8/1993	BUFS Case I.D.#81182154, Case#4126-petechiae to face; rash on forehead, back and hairline.	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
628.17	9/23/1991	BUFS Case I.D.#119008204, Case# 593-diaper rash, blisters in mouth and on lips, multiple vesicles on tongue, injected tonsils, swollen gums,	Lacks authentication (Rule 901)
628.18	5/13/1993	BUFS Case I.D.#91584555, Case#4509-EM, possible drug reaction, erythematous rash all over body, face, extremities; confluent lesions on upper extremities	Lacks authentication (Rule 901)
628.19	No date	Absolute Risk and Relative Risk calculation of Plaintiffs' Expert Review of BUFS hospitalized cases;	Lacks authentication (Rule 901)
628.2	No date	Line listings of Hospitalized BUFS cases involving severe mucocutaneous and/or cutaneous reactions	Lacks authentication (Rule 901)
628.21	2/15/1991	BUFS Case I.D.#0072-05/300021-Produced by Boston University-BU013-BU048	Lacks authentication (Rule 901)
628.22	2/19/1992	BUFS Case I.D.#32199, Case # 0601-09, Staph scalded-produced by Boston University, BU072-BU097;	Lacks authentication (Rule 901)
628.23	Dec-92	BUFS Case I.D.#64052933-EM/SJS-produced by Boston University, BU006-BU012	Lacks authentication (Rule 901)
628.24	3/22/1993	BUFS Case I.D.#095014-Impetigo lesions on legs and fingers; produced by Boston University-BU107-BU136	Lacks authentication (Rule 901)
628.25	8/31/1991	BUFS Case I.D.#11811, 055-21-EM, adverse effect of drug-produced by Boston University, BU071-BU070	Lacks authentication (Rule 901)
628.26	7/13/1992	BUFS Case I.D.#44826, Case#3044-18-bullous impetigo-rash, bullae and 2nd degree burn, drug rash-produced by Boston University, BU098-BU105	Lacks authentication (Rule 901)
628.27	12/22/1993	NDA 19-842 SNDA submission for Rx. To OTC Switch before changed to 20-516 with data listings, but not refiled under right NDA. CANDA, or Computer Automated New Drug Application submitted, Table I Specific Problems Prompting an outpatient visit in BUFS, included 2 cases of dermatitis exfoliative exposed to ibuprofen, 2 cases of stomatitis.	Lacks authentication (Rule 901)
628.28		Serious Outpatient skin reactions records from BUFS Patient Data Listings and Follow-ups	Lacks authentication (Rule 901)
629	No Date	The CSM ADEs	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
630	No Date	MCA adverse event reports	Lacks authentication (Rule 901)
631.1-.40	No Date	Domestic and foreign labels and warnings for different single ingredient ibuprofen products, including Pediaprofen Package Insert, Children's Motrin and other single ingredient ibuprofen products	Lacks authentication (Rule 901)
632	No Date	The Canadian HPB NSAID class warnings for SJS/TEN	Lacks authentication (Rule 901)
633	No Date	Spontaneous reports from McNeil for cases of EMS, SJS and TEN	Lacks authentication (Rule 901)
634-634.100	No Date	Promotional and advertising materials for Pediaprofen, Children's Motrin and other single ingredient ibuprofen products marketed by McNeil and J&J	Lacks authentication (Rule 901)
634.1		SJS Statement	Lacks authentication (Rule 901)
634.2	3/29/2005	Brands-Competition Power Point Slides with graphs comparison between APAP and IBU sales and sick kids	Lacks authentication (Rule 901)
634.3		pediatric Key Questions for 2006 Business Planning with Power Point slides	Lacks authentication (Rule 901)
		Time to Onset in Dr. Tackett's Report	
637	2007	Pichler, W;1 (ed): <u>Drug Hypersensitivity</u> . "Drug Hypersensitivity Reactions: Classification and Relationship to T-Cell Activation." Basel Karger, pp. 168489, (2007).	
638	2007	Pichler, WI (ed): <u>Drug Hypersensitivity</u> . "Maculopapular Drug Eruptions." Basel Karger, pp. 242-230, (2007).	
639	2007	Pichler, WJ (ed): <u>Drug Hypersensitivity</u> . "Drug-Induced Hypersensitivity Syndrome and Viral Reactivation." Basel, Karger, pp. 251-266, (2007).	
640	2007	Pichler, Wi (ed): <u>Drug Hypersensitivity</u> . "Approach to the Patient with a Drug Hypersensitivity Reaction-Clinical Perspectives." Basel, Karger, pp. 352-365, (2007).	
641	2000	Yamane, Icumiko, et al.: <u>Allergology International</u> . "Analysis of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Japan from 2000 to 200G." Japanese Society of Allergology, Vol. 56, No. 4, pp. 1-7, (2007).	

Exh No.	Date	Description	Defendants' Objections
642	2007	b. Patel, Raksha M, and Marfatia Y.S.: <u>Indian J Dermatol Venereol Leporl</u> . "Clinical study of Cutaneous eruption in 200 patients". 74:80, (2007).	
643	2004	Taghian, M, M.D., et al.: <u>The Journal of Pediatrics</u> . "Acute Vanishing Bile Duct Syndrome After Ibuprofen Therapy in a Child." <i>The Journal of Pediatrics</i> , pp. 273-276, (August 2004).	
644	2003	Pichler, INJ, M.D.: <u>Annals of internal Medicine</u> . "Delayed Drug Hypersensitivity Reactions?" American College of Physicians, Volume 139, Number 8, pp. 683-693, (October 2003).	
645	2003	Mockenhaupt, Maja, et al.: <u>The Journal of Rheumatology</u> . "The Risk of Stevens-Johnson and Toxic Epidermal Necrolysis Associated with Nonsteroidal Antiinflammatory Drugs: A Multinational Perspective." Volume 30, Number 10, pp. 2234-2240, (2003).	
646	2003	Naisbitt, Diean J., et al.: "Immunological Principles of Adverse Drug Reactions. The Initiation and Propagation of Immune Responses Elicited by Drug Treatment." <i>Drug Safety</i> , Volume 23, Number 6, pp. 483-507, (2003).	
647	1999	Fritsch, Peter O. and Ruiz-Maldonado Ramon: <u>Fitzpatrick's Dermatology in General Medicine</u> , 7 th ed. "Stevens-Johnson Syndrome---Toxic Epidermal Necrolysis." McGraw-Hill, Volume 1, pp. 644-654, (1999).	
648	1998	Paul, Chestier N. M.D., et al.: <u>Journal of Burn Care and Rehabilitation</u> . "Case Report: Oxaprozin and Fatal Toxic Epidermal Necrolysis." American Burn Association, Volume 19, Number 4, pp. 321-323, (1998).	
649	1996	Khoo, A.K.M. and C.L. Foo: <u>Burns</u> . "Toxic Epidermal Necrolysis in a Burns Centre: A 6-year review." Elsevier Science, Ltd., Volume 11, Number 4, pp. 275-278, (1996).	
650	1995	Sharma, Vinod K., et al.: <u>Pediatric Dermatology</u> . "Clinical Pattern of Cutaneous Drug Eruption among Children and Adolescents in North India". Volume 12, Number 2, pp. 178-183, (1995).	

Exh No.	Date	Description	Defendants' Objections
651	1989	Stern, Robert S., M.D. and Chan, Heng-Leong, M.D.: <u>Journal of the American Academy of Dermatology</u> . "Usefulness of Case Report Literature in Determining Drugs Responsible for Toxic Epidermal Necrolysis." Volume 21, pp. 317-322, (1989).	
652	1989	Bigby, Michael, M.D., et al.: <u>Primary Care</u> . "Allergic Cutaneous Reactions to Drugs." Volume 16, Number 3, pp. 713-727 (1989).	
653	1984	Wintroub, E.U. and R.S. Stern.: <u>Current Perspectives in Immunodermatology</u> . "Current Drug Reactions." Churchill Livingstone, pp. 74-97, (1984).	
654	1997	Stern, R. et al., <u>Arndt Dermatol Cutaneous Med & Surg in Primary Care</u> . "Cutaneous Drug Reactions." Chap. 18, pp. 85-89, (1997).	
655	1978	Sternleib, Peter, M.D., et al.: <u>New York State Journal of Medicine</u> . "Stevens-Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen." Volume 78, Number 8, pp. 1239-1243, (July 1978).	
666	No Date	STAR Literature Database printout Notebooks, Volumes 1-3	Lacks authentication (Rule 901)
670	1984	MC 67085	
673		NSAIDs Withdrawn Folder including FDA list of All drugs withdrawn for not being safe and effective	Lacks authentication (Rule 901)
674	No date	Index of 17 Publications that TEN is Solely Caused By Drugs Literature	Lacks authentication (Rule 901)
674.1	1987	Roujeau, JC, "Clinical Aspects of Skin Reactions to NSAIDs" J. Rheum., (Suppl. 65) 131-134, 132 (1987)	
674.2	1990	Roujeau, JC, "Toxic Epidermal Necrolysis (Lyell syndrome): Review," J Amer Acad Dermatol., 23(6), part 1:1039-1061, pp. 1039 & 1046 (1990)	
674.3	1990	Roujeau, JC, "Toxic Epidermal Necrolysis (Lyell syndrome)" Arch. Dermatol., 126:37-42, 41 (1990)	

Exh No.	Date	Description	Defendants' Objections
674.4	1993	Bastuji-Garin, Rzany, Stern, et. al., Archives of Dermatology, "Clinical Classification of Cases of Toxic Epidermal Necrolysis, Stevens-Johnson syndrome, and Erythema Multiforme, Vol. 129, 92-96, 92 (1993)	
674.5	1993	Correia, O, et al., "Evolving Pattern of Drug-Induced Toxic Epidermal Necrolysis," Dermatology, 186:32-57, 32 (1993)	
674.6	1994	Roujeau, et. al. "Severe Cutaneous Reactions to Drugs, NEJM, Vol. 331, No. 19, 1271-1285, 1273 (1994)	
674.7	1995	Assier, Bastuji-Garin, Revuz & Roujeau, "Erythema Multiforme With Mucous Membrane Involvement and Stevens-Johnson Syndrome Are Clinically Different Disorders With Distinct Causes", Arch. Dermatol., 131:539-543, 543 (1995)	
674.8	1997	Roujeau, JC, Rev. Rheum. [Engl. Ed.], "Severe Drug-Induced Blistering Disorders," Vol. 64 (1); pp. 5-9, 7 (1997)	
674.9	1997	Roujeau, JC, Journal of Dermatology, "Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis are Severity Variants of the Same Disease which differs from Erythema Multiforme," Vol. 24; pp. 726-729, 729 (1997)	
674.10	1997	Knowles, et. al., Current Opinions in Pediatrics, "Serious dermatologic reactions in children," 9:388-395, 391 (1997)	
674.11	2000	Schulz, Sheridan, Ryan, et al., "A Ten Year Experience with Toxic Epidermal Necrolysis", J. Burn Care & Rehabilitation, pp. 199-204, 199-200 (May/June 2000)	
674.12	2000	Garcia-Doval, et. al., Arch Dermatol, "Toxic Epidermal Necrolysis and Stevens Johnson Syndrome," Vol. 136, pp. 323-327, 324 (2000)	
674.13	2001	Paquet, P, et al., "Treatment of Drug-induced toxic epidermal necrolysis (Lyell's syndrome) with intravenous human immunoglobulins," Burns, pp. 652-655 (2001)	
674.14	2002	Foreman, et. al., Drug Safety, "Erythema Multiforme, Stevens-Johnson syndrome and Toxic Epidermal Necrolysis in Children," 25 (13) 965-972, 966 & 969 (2002)	

Exh No.	Date	Description	Defendants' Objections
674.15	2005	FDA-Legrenade, et al. Drug Safety, "Comparison of Reporting of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Association with Selective COX-2 Inhibitors", 28 (10); 917-924, 922 (2005)	
674.16	2009	Mockenhaupt, et al., Academy, "Severe drug-induced skin reactions: clinical pattern, diagnostics and therapy" 7:142-162, 144 (2009)	
674.17	2009	Mockenhaupt, et al., Academy, "Severe drug-induced skin reactions: clinical pattern, diagnostics and therapy" 7:142-162, 144 (2009)	
677		Folder-STAR Literature Database Table	Lacks authentication (Rule 901)
678	No Date	American Pharmaceutical Association Product Bulletin on Children's Motrin;	Lacks authentication (Rule 901)
679	No Date	Comprehensive Review of the Safety of Ibuprofen in Pediatric Patients; Including MC 67244	Lacks authentication (Rule 901)
680.1	1993	3/29/93 DDMAC letter to McNeil regarding Children's Motrin;	
680.2	1993	5/20/93 DDMAC letter to McNeil regarding Children's Motrin;	
680.3	1995	5/9/95 DDMAC letter to McNeil regarding Children's Motrin;	
680.4	1995	6/14/95 DDMAC letter to McNeil regarding Children's Motrin;	
680.5	1995	6/16/95 DDMAC letter to McNeil regarding Children's Motrin;	
680.6	1995	7/13/95 DDMAC letter circulated by Pagsuyin re CM	
681	No Date	Materials from Anthony Temple, M.D.'s files, including; the Goldfrank and Koberly reports, MC063066-072241	Lacks authentication (Rule 901)
681.51	1984	Goldfrank Report: Bellevue Hospital Center Letter to Anthony R. Temple, best updating on ibuprofen from Lewis Goldfrank, dated September 12, 1984	
681.52	1983	Korberly Report: Ibuprofen Review prepared for: David E. Collins by Marsha M. Silberstein, M.D., Barbara H. Korberly, Pharm D. dated August 12, 1983	

Exh No.	Date	Description	Defendants' Objections
682.1	1984	3/21/84 McNeil Citizen's Petition and FDA response against Advil Rx. to OTC Switch;	
682.2	1984	4.12.84 Supp. To McNeil CP	
682.3	1984	5.1.84 Memo of Meeting Between McNeil, J&J & FDA	
682.4	1984	5.2.84 McNeil Letter to FDA re Petition	
682.5	1984	5.7.84 J&J Memo summarizing meeting with FDA	
682.6	1984	5.24.84 McNeil v. Heckler (FDA Commissioner) Complaint	
682.7	1984	7.27.84 McNeil Surreply	
682.8	1984	9.7.84 FDA Response to McNeil Petition referencing McNeil v. Heckler	
682.9	1984	9.20.84 J&J Letter to FDA re FDA's response regarding McNeil v. Heckler	
683	1983	8/18-19/83 Minutes of the 17th Arthritis Advisory Committee and 8.9.93 Judith Jones report with handouts to FDA Advisory Committee regarding skin reactions;	
684.1	No Date	American Home Products presentation materials on safety and efficacy of ibuprofen;	Lacks authentication (Rule 901)
684.2	1983	9/19/83 McNeil Letter and submission commenting on AHPs presentation of materials to FDA	
685	No Date	FDC reports on Motrin and ibuprofen products;	Lacks authentication (Rule 901)
686	No Date	Pre-NDA and Pre-Approval meeting notes/correspondence for Pediaprofen and Rx. to OTC Switch for Children's Motrin	
688	2009	McNeil - Briefing Materials for Drug Safety and Risk Management Anesthetic and Life Support and Non-Prescription Drugs Advisory Committee Meeting June 29-30, 2009.	
688.1	2-16/2005-2/18/2005	Transcripts and word indexes from Joint Advisory Committee Hearings on NSAIDs	Lacks authentication (Rule 901)
688.2	2/16-2/18/2005	Official Agenda and Minutes from Joint Advisory Committee Meetings on NSAIDs	Lacks authentication (Rule 901)
688.3		Jt. Committee transcript on dexibuprofen	Lacks authentication (Rule 901)
689	No Date	McNeil/J&J Safety policies and procedures for adverse experience reporting	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
690-690.500	No Date	Annual and Periodic Reports for NDAs 19-842, 20-516, 17-463, 19-899, 19-012, 20-601, 20-602, 20-603, 21-128	
691.1	No Date	Adult Motrin Label; CDER Guidance 4786LAI.PDI, Example Drug Facts Label for Ibuprofen 200 mg in a Tablet / Capsule Dosage Form	
691.2	No Date	PDR page 1684 Motrin IB	
691.3	No Date	Children's Motrin, Berry flavor, 100 mg, Ibuprofen oral suspension, 1120102	Lacks authentication (Rule 901)
691.4	No Date	Children's Motrin, www.motrin.com/products/children Home web page, 2/13/2003	Lacks authentication (Rule 901)
691.5	No Date	Children's Fever, Health Articles, www.motrin.com/verc/atricale.ihtml?id, Consumer Relationship Center, 11/01/2002	Lacks authentication (Rule 901)
691.6	No Date	Nick Jr. Parents, www.nickjr.com/parenting/health , C.A.L.M. Fever Guide, "Helpful Advice from our sponsor Johnson & Johnson, 11/18/2003	Lacks authentication (Rule 901)
691.7	No Date	Children's Motrin Ibuprofen oral suspension 100 mg packing, McNeil Consumer Products, Co.@McN-PPC, Inc. '98	Lacks authentication (Rule 901)
691.8	No Date	Children's Flu, Health Articles, www.motrin.com/vcre/article.html?id, Symptoms & Conditions, Children's, Flu, Consumer Relationship Center, 11/1/02	Lacks authentication (Rule 901)
691.9	No Date	Children's Motrin www.motrin.com/products/children/detail.ihtml?id, Availability Uses, Directions Home page, 1111/02	Lacks authentication (Rule 901)
691.10	No Date	Children's Motrin, Canada, www.motrin.ca/eng/home.html , home Page, 1111/02	Lacks authentication (Rule 901)
691.11	No Date	Children's Motrin, Canada, www.motrin.ca/eng/child/productoverview.html , Overview Up to 8 Hour Fever Relief Page, Availability, 11/1/02	Lacks authentication (Rule 901)
691.12	No Date	Children's Motrin, Canada, www.motrin.ca/eng/child/products/chilts.html , Formats & Flavours, Children's Motrin* Chewable Tablets	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
691.13	No Date	Center for Drug Evaluation and Research, Application Number: S-003, Approved Labeling	
691.14	No Date	<u>Children's Motrin To Market Expanded OTC Pediatric Ibuprofen Line, PR Newswire, www.kidsource.com/kidsource/content/news/motr in6 29 96.html, 4/4/2003</u>	Lacks authentication (Rule 901)
691.15	No Date	Children's Motrin Ibuprofen oral suspension 100 mg packing, @MCN-PPC, Inc. '01	Lacks authentication (Rule 901)
691.16	No Date	Chap Stick label, Skin Protection I Sunscreen SPF-4	Lacks authentication (Rule 901)
691.17	No Date	Supplemental new drug applications dated June 1, 1998, Department of Health & Human Services, (1999)	Lacks authentication (Rule 901)
691.18	No Date	Survey Highlights Important Information About Over-the-Counter Pain Relievers, Aphanet.org, APhA Partnership Joins Pharmacists with Consumers In Educational Effort, 6/17/2003	Lacks authentication (Rule 901)
691.19	No Date	Dockets Management Branch, Food and Drug Administration, NKF National Foundation, Making Lives Better, response to the Proposed Rule, "Internal Analgesic, Antipyretic Drug Products for Over-the-Counter Human Use, 77N-0941 C2	Lacks authentication (Rule 901)
691.20	No Date	Ibuprofen Coated Tablets, USP, Non-Prescription Strength, Pain reliever / Fever reducer, Pain Relief Formula, 200 mg, novopharm, 7/20/1998	Lacks authentication (Rule 901)
691.21	No Date	Children's Advil Suspension, Ibuprofen 100 mg, Drug Facts, <u>www.advil.com/childrens/Pain/sus label.asp</u> , 4/7/2004.	Lacks authentication (Rule 901)
691.22	No Date	<u>Search Medline Plus, MedlinePlus Drug Information: Ibuprofen, www.nhn.nih.gov/medlineplus/druginfo/medmaster/a682159.html, 3/15/2004</u>	Lacks authentication (Rule 901)
691.23	No Date	<u>Material Safety Data Sheet, Product Number:375160, Product Name:(S)-(+)-4-Isobutyl-a-methylphenylacetic acid 99%, Aldrich Chemical Co. Inc, http://www.uiowa.edu/~chemsafel, MSDS/Ibuprofen, Valid 02/200 - 04/2000, printed on 1/30/2004</u>	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
691.24	No Date	Guidance for Industry, "Labeling OTC Human Drug Products Updating Labeling in ANDAs, Draft Guidance, HHS, FDA, CDER, OTC, (February 2001)	
691.25	No Date	Guidance for Industry, "The Content and Format for Pediatric Use Supplements"	
691.26	No Date	Mockenhaupt, et. al, <u>J. Rheumatology</u> , SCAR Study Group, Label, pp. 30:2234, (2003)	
691.27	No Date	Federal Register, Rules and Regulations, HHS, FDA, 21 CFR Parts 201, 330, 331, 341, 346, 355, 358, 369, and 701, [Docket Nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201, Display Date: 3-11-99@11:59, Publication Date: 3-17-99	
691.28	No Date	Federal Register, Part II Department of Health and Human Services, FDA, 21 CFR Part 201, et. al., Over-The-Counter Human Drugs; Labeling Requirements; Final Rule, (March 1999)	
691.29	No Date	Federal Register, Vol. 67, No. 162, Wednesday, August 21, 2002 Proposed Rules, HHS, FDA 21 CFR Part 201, [Docket No. 02N-0241), pp 54139 - 54159,	
691.30	No Date	Federal Register, Vol. 71, No. 247 Tuesday, December 26, 2006 I Proposed Rules, HHS, FDA, 21 CFR Parts 201 and 343, [Docket No. 1977N-0094L)	
691.31	No Date	FDA Campaign on Safe Use of Analgesics and Antipyretics, FDA Patient Safety News: Show #26, www.accessdata.fda.gov/scripts/ledrhlc.fdocs/psn/printer.cjm?id=216 , April 2004	Lacks authentication (Rule 901)
691.32	No Date	Federal Register, Vol. 74, No. 81 / Wednesday, April 29, 2009 / Rules and Regulations, HHS, FDA 21 CFR Part 201, [Docket No. FDA -- 1977 - N - 0013] (formerly Docket No. 1977N-0094L), pages 19385 - 19409, 4/29/2009	

Exh No.	Date	Description	Defendants' Objections
		Dr. Tackett's Scientific Literature Causal Relationship of Ibuprofen to SJS & TEN; Ibuprofen and Hepatotoxicity Notebook; Pharmacogenic Ibuprofen; Ibuprofen Medical Research Notes; Viral plus drug induced HSR SJS & TEN; Madden Medical Research Notebooks, Pharmacogenetics; Submissions of Scientific Data by McNeil/J&J to FDA and worldwide regulatory authorities	
692	2010	Nanau, Radu M. et al., <u>Translational Research</u> , "Ibuprofen-induced hypersensitivity syndrome"; 155.275-293, (2010)	
693	2009	Levi, Natachar et al., <u>Pediatrics</u> , "Medications as Risk Factors of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Children: A Pooled Analysis," Vol. 123, No. 2, pp: e297-e304, (2009)	
694	2009	Rijal, A. et al., Indian Journal of Dermatology, Verrereology and L e Tab 3 "Outegrne° of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis treated with Corticosteroids," Vol: 75, pp. 613-614, (2009).	
695	2009	Goyal, S., et al., <u>J Burn Care Res</u> , "Toxic Epidermal Necrolysis in Children: Medical, Surgical, and Ophthalmologic Considerations," Vol. 30, pp. 437-449, .(2009).	
696	2008	Salvo;.F., et al., <u>Pharmacological Research</u> , "Allergic Reactions to Oral Drugs: A Case/non Case from an Italian Spontaneous Reporting Database (GIF),"Doi :10:1016/j.ph 2008.07.003,pp. 1-6 (2008)	
697	2008	Yuri, Soak Jung, et. al., <u>Dermatology</u> , "Serum Lactate Dehydrogenase Is A Novel Maker for the Evaluation of Disease Severity in the Early Stage of Toxic Epidermal Necrolysis," 17:254-259,(2008)	
698	2008	Sharma V., et: al., <u>Indian J. Dermatol Venereol Leprol</u> , "Stevens Johnson syndrome, toxic epidermal necrolysis (TEN) and SJS-TEN overlap: A retrospective study of causative drugs and clinical outcome," 74;238-40, (2008)	

Exh No.	Date	Description	Defendants' Objections
699	2008	Cheigh, Nina H. et al, <u>Pharmacotherapy: A Pathophysiologic Approach</u> , 7th Edition, "Chapter 99: Dermatologic Drug Reactions and Self Treatable Skin Disorders", pp. 1-31, (2008)	
700	2008	Raksha, M: Patel, et al, <u>Indian J Dermatol Venereology Leprology</u> , "Clinical Study of Cutaneous Drug Eruptions in 200 Patients," 74:80, (2008)	
700.2	No Date	Index of 57 Publications or Articles entitled SCIENTIFIC LITERATURE ON THE RELATIONSHIP OF IBUPROFEN TO SJS AND TEN	
700.3	1989	Stern, R, et al, <u>Pharmacol Skin</u> , "Adverse Cutaneous Reactions to nonsteroidal Anti-Inflammatory Drugs", Vol 2, pp 148-156, 151 (1989)	
701	2008	Mockenhaupt, Maja, et al., <u>Journal of Investigative Dermatology</u> , "Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Assessment of Medication Risks with Emphasis on Recently Marketed Drugs. The EuroSCAR-Study, 128, 35-44, (2008).	
702	2007	Mockenhaupt, Maja, et. al., <u>Journal of Investigative Dermatology</u> , advanced online publications, "Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: Assessment of Medication Risks with Emphasis on Recently Marketed Drugs, The EuroSCAR-Study", Vol. 128, 35-44 (2007)	
703	1996	Gaist, et al., Spontaneous Reports of Drug-Induced Erythema Multiforme, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Denmark 1968-1991, PHARMACOEPIDEMIOLOGY AND DRUG SAFETY. VOL. 5: 79-86 (1996)	
704	2007	The EuroSCAR-Study", Supplementary Material, Table 51 Matched Analyses, Table 52 Alerts, Table 53 Drugs-<used:,by at least 1.5°%0 of controls (multivariate, unmatched analysis), Received 12 May 2006; Revised 19 April 2007; .Accepted 19 April 20074 published online 6 September 2007, doi:10.10381sj.jid.5701033, pp. 1-10, (2007)	

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735.13	1973	Brooks C., et al., <u>Current Therapeutic Research</u> , "Tolerance and Pharmacology of Ibuprofen," Vol, 15, No, 4, pp. 180-90, (1973)	
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738.1	approx 1984	McNeil's Response to Docket No. 1977N-0094L, FDA-Proposed Rule IAAA; and see Briefing (Certified) and referenced at para. 45/46 of Dr. Tackett's Report	Lacks authentication (Rule 901)
738.2	6/29-30/2009	McNeil Tylenol Briefing Document, Acetaminophen Advisory Committee Meeting, Briefing Materials for Drug Safety and Risk Management	Lacks authentication (Rule 901)
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776	2000	Mascagni P., et al., <u>Eur Cytokine Netw</u> , "R-and S-Isomers of Non-steroidal Anti-inflammatory Drugs Differentially Regulate Cytokine Production," Vol. 11, No. 2, pp.185-92, (2000)	
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788	2003	Teoh N., et al., <u>Clin Liver Dis</u> , "Hepatotoxicity Associated with Non-Steroidal Anti-inflammatory Drugs," Vol. 7, pp. 401-43, (2003)	
789	2003	2003 AERS Ibuprofen Liver Complications	Lacks authentication (Rule 901)
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791	2004	2004 AERS Ibuprofen Liver Complications	Lacks authentication (Rule 901)

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792		Mockenhaupt documents produced at her oral deposition taken in Karen Robinson versus McNeil/SJS	
792.1	2000	ISPE Poster Presentation-Antirheumatic diseases and NSAIDs/SJS-TEN-SCAR study	
792.2	2011	Trelle, et al. BMJ article on ibuprofen and MI, Stroke risks, BMJ 2011;342c:c7086	
793-893		Waller & Lee, PC, et al., "Responding to Drug Safety Issues," Pharmacepidemiology and Drug Safety, 1999, 8; pp. 535-552 & FDA Regulation and FDA Guidance Documents; Literature on Pharmacology Procedures; Safety Signal Detention Methods, Casual Algorithms, Proportional Reporting Ratios, Data Mining, Aggregate Safety Data Review and Pre-Marketing Risks and Safety \ Risk communication to HealthCare Professional and Public (as produced at his depositions)	
894.1 & 894.2		McNeil Product Safety Reviews-PSURs	Lacks authentication (Rule 901)
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902	2003	Hutt, A., et al., <u>Acta Facultatis Pharmaceuticae Universitatis Comenianae</u> , "The Chiral Switch: The Development of Single Enantiomer Drugs From Racemates," pp. 7-23, (2003)	
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906	2002	Posadas S., et al., <u>Blood Cells, Molecules & Diseases</u> , "Gene Expression Levels of Cytokine Profile and Cytotoxic Markers in Non-Immediate Reactions to Drugs," Vol. 29, No. 2, pp. 179-89, (2002)	
907	2001	Paquet P., et al., <u>Burns</u> , "Treatment of Drug-Induced Toxic Epidermal Necrolysis (Lyell's Syndrome) With Intravenous Human Immunoglobulins," Vol. 27, pp. 652-5, (2001)	
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909	2001	Phleps W., <u>Clin Rheumatol</u> , "Overview on Clinical Data of Dexibuprofen," Suppl 1, pp. S15-S21, (2001)	
910	2001	Evans A., <u>Clin Rheumatol</u> , "Comparative Pharmacology of S(=)-Ibuprofen and (RS)-Ibuprofen," Suppl 1, pp. S9-14, (2001)	

Exh No.	Date	Description	Defendants' Objections
911	2000	Singer F., et al., <u>Inter Jour of Clin Pharma & Therapeutics</u> , "Evaluation of the Efficacy and Dose-Response Relationship of Dexibuprofen (S(+)-Ibuprofen) in Patients with Osteoarthritis of the Hip and Comparison with Racemic Ibuprofen Using the WOMAC Osteoarthritis Index," Vol. 38, No. I, pp. 15-24, (2000)	
912	2000	<u>Trent DIS</u> , "DI Dispatch: A Current Awareness Newsletter," pp. 1-7, (2000)	
913	2000	Bon A., et al., <u>Clin Rheumatol</u> , "Treatment of Non-Malignant Pain in the Dutch GP Population: An Analysis of Treatment Standards, Prescription Habits and Basic Attitudes," Suppl 1, pp. S2-5, (2000)	
914	2000	Mascagni P., et al., <u>Eur Cytokine Netw</u> , "R- and S-Isomers of Nonsteroidal Anti-Inflammatory Drugs Differentially Regulate Cytokine Production," "Vol. 11, No. 2, pp. 185-92, (2000)	
915	1999	Fritsch P., et al., <u>Fitzpatrick's Dermatol in Gen Med</u> , "Stevens-Johnson Syndrome-Toxic Epidermal Necrolysis," Chap. 59, pp. 644-54, (1999)	
916	1999	Luster M., et al., <u>Critical Reviews in Toxicology</u> , "Tumor Necrosis Factor a and Toxicology," Vol. 29, No. 5, pp. 491-511, (1999)	
917	1999	Arnold R., et al., <u>Jour of Immunology</u> , "Crosstalk Between Keratinocytes and T Lymphocytes Via Fas/Fas Ligand Interaction: Modulation by Cytokines," pp. 7140-7, (1999)	
918	1998	Viard I., et al., <u>Science</u> , "Inhibition of Toxic Epidermal Necrolysis by Blockade of CD95 with Human Intravenous Immunoglobulin," Vol. 282, pp. 490-3, (1998)	
919	1998	Wolkenstein P., et al., <u>Lancet</u> , "Randomized Comparison of Thalidomide Versus Placebo in Toxic Epidermal Necrolysis," Vol. 352, pp. 1586-89, (1998)	
920	1997	<u>OTC Business News</u> , "Reform Boost to Austrian Market?" pp. 1-2, (1997)	
921	1997	<u>Pharma Marketletter</u> , "Spirig Gains First Approval for S-Optifen," pp. 1, (1997)	

Exh No.	Date	Description	Defendants' Objections
922	1997	Walker P., et al., <u>Jour of Immunology</u> , "Role of Fas Ligand (CD95L) in Immune Escape the Tumor Cell Strikes Back," Vol. 158, pp. 4521-24, (1997)	
923	1997	Paquet P., et al., <u>Amer Jour of Dermatol</u> , "Erythema Multiforme and Toxic Epidermal Necrolysis: A Comparative Study," Vol. 19, No. 2, pp. 127-32, (1997)	
924	1997	Salomon D., et al., <u>Annales De Dermatol</u> , "Five Cases of Toxic Epidermal Necrolysis Treated by Intravenous Immunoglobulins with Favorable Results," Suppl 124, pp. S216-17, (1997)	
925	1996	Rahlf V., et al., <u>J Clin Pharmacol</u> , "Reevaluation of Some Double-Blind, Randomized Studies of Dexibuprofen (Seractil): A State-of-the-Art Overview," Vol. 36, pp. 33S-40S, (1996)	
926	1996	Paul C., (Wolkenstein & Roujeau) et al., <u>Brit Jour of Dermatol</u> , "Apoptosis as a Mechanism of Keratinocyte Death in Toxic Epidermal Necrolysis," Vol. 134, pp. 710-14, (1996)	
927	1996	Klausner J., et al., <u>Clin Immunology & Immunopathology</u> , "Short Analytical Review: Thalidomide as an Anti-TNF- α Inhibitor: Implications for Clinical Use," Vol. 81, No. 3, pp. 219-23, (1996)	
928	1996	Evans, A., <u>Clin Pharmacol</u> , "Pharmacodynamics and Pharmacokinetics of the Profens: Enantioselectivity, Clinical Implications, and Special Reference to S(+)-Ibuprofen," Vol. 36, ppp. 7S-15S, (1996)	
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930	1994	Paquet P1., et al., <u>Arch Dermatol</u> , "Macrophages and Tumor Necrosis Factor α in Toxic Epidermal Necrolysis," Vol. 130, pp. 605-16, (1994)	
931	1991	Ertel W., et at., <u>Jour of Trauma</u> , "Eicosanoids Regulate Tumor Necrosis Factor Synthesis After Hemorrhage in Vitro and In Vivo," pp. 609-16, (1991)	

Exh No.	Date	Description	Defendants' Objections
932	1991	Evans A., et al., <u>J Clin Pharmacol</u> , "Effect of Racemic Ibuprofen Dose on the Magnitude and Duration Platelet Cyclo-Oxygenase Inhibition: Relationship Between Inhibition of Thromboxane Production and the Plasma Unbound Concentration of S(+)-Ibuprofen," Vol. 31, pp. 131-8, (1991)	
933	1989	Pang Y., et al., <u>Australian Prescriber</u> , "Stereoisomerism in Drug Molecules," Vol. 12, No. 1, pp. 19-25, (1989)	
934	2002	New Medicines Authorized in Spain in 2002	Lacks authentication (Rule 901)
935	No Date	Package Inserts for Seractil	Lacks authentication (Rule 901)
941	No Date	Dolormin fur Kinder Ibuprofensaft'4%	Lacks authentication (Rule 901)
942	No Date	Advil Suspension enfants & noumfins	Lacks authentication (Rule 901)
943	No Date	Generico ADVIL Ibuprofeno	Lacks authentication (Rule 901)
944	No Date	Generico ADVIL Ibuprofetiib Suspension	Lacks authentication (Rule 901)
945	No Date	Generico ADVID Ibuprofeno 50mg, 100mg	Lacks authentication (Rule 901)
946	No Date	Professional Information Spalt Liqua Migraine	Lacks authentication (Rule 901)
947	No Date	German PILs English	Lacks authentication (Rule 901)
948	No Date	German PILs German	Lacks authentication (Rule 901)
949	No Date	Adult Labeling German Spalt Liqua	Lacks authentication (Rule 901)
950	No Date	Dear User Letter Spalt Liqua	Lacks authentication (Rule 901)
951	No Date	Professional Information Spalt Liqua Forte	Lacks authentication (Rule 901)
952	No Date	Active ingredient Ibuprofen Spalt Liqua, Migrane	Lacks authentication (Rule 901)
953	No Date	Advil Gel 5% Ibuprofen packaging	Lacks authentication (Rule 901)
954	No Date	Anadvil Ibuprofen 200mg packaging	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
955	No Date	Adult Labeling for Germany	Lacks authentication (Rule 901)
956	No Date	Arabic Advil for Children Ibuprofen S Syrup	Lacks authentication (Rule 901)
957	No Date	Bulgaria PIL Advil,200mg	Lacks authentication (Rule 901)
958	No Date	Belgium & Luxemborg Advil PILs 400 & 200mg	Lacks authentication (Rule 901)
959	No Date	Brazil Adult Labeling	Lacks authentication (Rule 901)
960	No Date	Brazil Children's Labeling	Lacks authentication (Rule 901)
961	No Date	Brazil Adult Labeling packing	Lacks authentication (Rule 901)
962	No Date	Brazil Children's packing	Lacks authentication (Rule 901)
963	No Date	Budapest Advil 200 mg coated tablets	Lacks authentication (Rule 901)
964	No Date	ETOS Ibuprofen 200 & 400 mg	Lacks authentication (Rule 901)
965	No Date	Dutch Adult Labeling Advil Oval 400	Lacks authentication (Rule 901)
966	No Date	France Adult Labeling French	Lacks authentication (Rule 901)
967	No Date	France Adult Labeling English	Lacks authentication (Rule 901)
968	No Date	France Children's Labeling Advil 20mg	Lacks authentication (Rule 901)
969	No Date	France Pediatric drops Advil for Infants	Lacks authentication (Rule 901)
970	No Date	Hungary Advil PIL	Lacks authentication (Rule 901)
971	No Date	Hungary Advil Liqui-Gels 200mg	Lacks authentication (Rule 901)
972	No Date	Hungary Advil Liqui-Gels 200mg	Lacks authentication (Rule 901)
973	No Date	Italy, Benelux PILS Advil, 400mg Tablets	Lacks authentication (Rule 901)
974	No Date	Romania, Adult 200 mg filmcoated labeling	Lacks authentication (Rule 901)
975	No Date	Romania, Adult 400 mg filmcoated labeling	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
976	No Date	Romania, Advil lozenges	Lacks authentication (Rule 901)
977	No Date	PIIE The Pharmaceutical Information Examiner	Lacks authentication (Rule 901)
978	No Date	Spanish Agency of Medicine Labeling	Lacks authentication (Rule 901)
979	No Date	Swedish, Seractil 200, 300, 400 mg Swedish	Lacks authentication (Rule 901)
980	No Date	Swedish, Seractil 200, 300, 400 mg English	Lacks authentication (Rule 901)
1001	2005	Correspondence between FDA and Wyeth regarding adding a warning about SJS to OTC label, and Wyeth's filing of serious skin reactions in May of 2005	Lacks authentication (Rule 901)
1002	No Date	Adverse event data concerning acetaminophen products	Lacks authentication (Rule 901)
1003.1	No Date	NDA 17-463 Clinical trial data, case reports and ADEs	Lacks authentication (Rule 901)
1003.2	No Date	Supplemental Applications and clinical trial data and ADEs	Lacks authentication (Rule 901)
1003.3	No Date	Quarterly Updates and Bi-Annual reports to NDA 17-463	Lacks authentication (Rule 901)
1003.4	No Date	Postmarketing Adverse Experiences from NDA 17-463	Lacks authentication (Rule 901)
1003.5	No Date	Progress reports for Clinical trial data for NDA 17-463	Lacks authentication (Rule 901)
1003.6	No Date	Annual and Periodic ADE reports for 17-463	Lacks authentication (Rule 901)
1003.7	No Date	NDA 19-012 Clinical trial data, case reports and ADEs	Lacks authentication (Rule 901)
1003.8	No Date	Supplemental Applications and clinical trial data and ADEs; Motrin Migraine	Lacks authentication (Rule 901)
1003.9	No Date	Quarterly Updates and Bi-Annual reports to NDA 19-012	Lacks authentication (Rule 901)
1003.10	No Date	Postmarketing Adverse Experiences from NDA 19-012	Lacks authentication (Rule 901)
1003.11	No Date	Progress reports for Clinical trial data for NDA 19-012	Lacks authentication (Rule 901)
1003.12	No Date	Annual and Periodic ADE reports for 19-012	Lacks authentication (Rule 901)
1003.13	No Date	FDA Correspondence, SNDAs and CBE changes for Motrin IB, Nuprin or Haltran products	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
1003.14	No Date	Submissions in Response to FDA requests to add SJS/TEN warnings to FDA	Lacks authentication (Rule 901)
1104	No Date	McNeil Safety Policies and Procedures for Adverse Event Collection and Reporting ADEs; CRS data entry and retrieval; Safety Information Exchange between McNeil/J&J and Pharmacia & Upjohn (PNU);	Lacks authentication (Rule 901)
1105	2003	SCEPTRE Administration & Operations Manual - LM007724-7773 April of 2003	
1106	2003	SCEPTRE Local Administration (foreign) Manual- LM007775-7794 April 25, 2003	
1107	No Date	SCEPTRE -Global Administration Training Manual-LM007795-7833 No date	
1108	No Date	SCEPTRE -Getting Started with Sceptre-LM007542-7568 No date.	
1109	No Date	Foreign reporting between PNU and McNeil; and other McNeil and J&J safety policies	Lacks authentication (Rule 901)
1110	No Date	Foreign reporting between PNU and McNeil; and other McNeil and J&J safety policies	Lacks authentication (Rule 901)
1111	No Date	Spontaneous Reports of Serious Skin and liver reactions	Lacks authentication (Rule 901)
1112	No Date	Source documents; emails between McNeil PV and upper management.	Lacks authentication (Rule 901)
1113-1133	No Date	Pharmacovigilance and pharmacoepidemiology practices and guidelines	Lacks authentication (Rule 901)
1133.1	1997	U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER, "Guidance for Industry - Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report", CLIN4, pp. MUT04268 MUT04267, (1997)	
1133.2	1998	Mackay, Fiona Jean, Drug Safety, "Post-Marketing Studies The Work of the Drug Safety Research Unit," 19 (5): pp. 343 353, (1998)	
1133.3 & 1133.31	1998	Council for International Organizations of Medical Sciences,. "Report of CIOMS Working Group IV, "Benefit - Risk Balance for Marketed Drugs: Evaluating Safety Signals", pp. 1 -74, Geneva (1998) & CIOMS V	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
1133.4	1998	Olsson,. Steil, Dx g Safety. "The Role of the WHO Programme on International Drug Monitoring in Coordinating Worldwide Drug Safety Efforts", 19(1); pp. 1 -10, (1998)	
1133.5	1999	Waller, Patrick, et. al, Pharmacoepidemiology and Drug Safety, "Responding to Drug Safety Issues, " Vol. 8, pp. 535- 552, (1999)	
1133.6	1999	Meyboom, Ronald H.B., et. al: Drug Safety, "Pharmacovigilance in Perspective," 21 (6): pp. 429 - 447, (1999)	
1133.7	2000	Lindquist, Marie; et. al, Drug Safety, "A Retrospective Evaluation of a Data Mining Approach to Aid Finding New Adverse Drug Reaction Signals in the WHO International Database," 23 (6): pp. 533 - 542, (2000)	
1133.8	2000	U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER), "Guidance for Industry - Content and Format of the Adverse Reactions Section of Labeling For Human Prescription Drugs and Biologics", DRAFT GUIDANCE This guidance document is being distributed for comments purposes only, pp 1 12, (2000)	
1133.9	2001	U.S. Department of Health and Human Services,. Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research, (CBER). 'Guidance for Industry - Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines", DRAFT GUIDANCE This guidance document is being distributed for comment purposes only, pp. 1 - 40, (2001)	
1133.10	2001	MedWatch; The FDA Medical Products Reporting Program, Official Reporting Document, Appendixes C thru F (2001)	Lacks authentication (Rule 901)
1133.11	2001	Ozdemir, Vural, et. al, Drug Safety, "What Will Be the Role of Pharmacogenetics in Evaluating Drug Safety and Minimising Adverse Effects?," 24 (2): pp 75 -- 85, (2001)	

Exh No.	Date	Description	Defendants' Objections
1133.12	2002	Egberts, Antoine C.G., et. al, Drug Safety, "Use of Measures of Disproportionality in Pharmacovigilance Three Dutch Examples," 25 (6): pp 453 458, (2002)	
1133.13	2002	Nelson, Robert C., et. al., Drug Safety, "Good Pharmacovigilance Practices Technology Enabled," 25 (6), pp. 407 -414, (2002)	
1133.14	2002	Szarfinan, Ma, et. al., Daft "Use of Screening Algorithms and . Computer Systems to Efficiently Signal Higher-Than-Expected Combinations of Drugs and Events in the US FDA's Spontaneous Reports Database," 25 (6): pp. 381- 392, (2002) '	
1133.15	2002	Purcell, Patrick, et. al, Drug Safety, "Statistical Techniques for Signal .Generation The Australian Experience," 25 (6): pp 415 - 421, (2002)	
1133.16	2003	Stahl, Malin, et. al, Drug Safety,, "Assessing the Impact of Drug Safety Signals from the WHO Database Presented in 'SIGNAL' Results from a Questionnaire of National Pharmacovigilance Centres," 26 (10),pp 721 - 727, (2003)	
1133.17	2003	Van Puijenbroek, Eugene P., et, al, Drug Safety "Application of Quantitative Signal Detection in the Dutch Spontaneous Reporting System for Adverse Drug Reactions," 26 (5), pp. 293 -3(11, (2003)	
1133.18	2003	Hauben, Manfred, et, at, Drug safety, "Quantitative Methods in Pharmacovigilance Focus on Signal Detection," 26 (3), pp. 159 -186, (2003)	
1133.19	2003	ICH International Conference on Harmonisation Of Technical Requirements For Registration Of Pharmaceuticals For Human Use, 'WHIM: Pharmacovigilance Planning (PvP) Draft Version 4.1 dated on November 2003", pp. 1 - 15, (2003)	Lacks authentication (Rule 901)
1133.20	2003	Dockets Management Branch (HFA-305) Food and Drug Administration "CONCEPT PAPER Risk Assessment of Observational Data: Good Pharmacovigilance Practices and Pharmacoepidemiologic-Assessment' DRAFT - This concept paper is being distributed for comment purposes only pp. 1- 13, (2003)	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
1133.21	2003	Holden, William L., Drug Safety, "Benefit-Risk Analysis - A Brief Review and Proposed-Quantitative Approaches", 26(12), pp. 853 --862, (2003)	
1133.22	2004	International Committee On Harmonisation Of Technical Requirements For Registration of Pharmaceuticals For Human Use, "ICI-I Harmonised Guideline -- Pharmacovigilance Planning, E2E", pp: 1 -16, (2004)	
1133.23	2004	19, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER), "Guidance for Industry -- Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment", Draft Guidance", pp.. 1.-19, (2004)	
1133.24	2004	Hauben, Manfred, The Annals of Pharmacotherapy "Early Postmarketing Drug Safety Surveillance: Data Mining Points to Consider," www,thearinala .com doi; 10.13451pph.1E023, pp. 1625-1630	
1133.25	2004	Soller, R. William, Drug Safety, "Adverse Experience Reporting for OTC Medicines Scientific /Regulatory Framework and Review of a Hypothetical Case Study," Vol. 38, pp. 157 - 169, (2004)	
1133.26	2004	Yee, Chuen L.et. al., Drug Information Journal, "Practical Considerations in Developing an Automated Signaling Program within a Pharmacovigilance Department," Vol. 38, pp. 293 -300, (2004).	
1133.27	2004	Hauben, Manfred, et al, Drug Safety,. "Safety Related. Drug-Labeling Changes: Findings From Two Data Mining Algorithms," 27 (10): pp. 735-744	
1133.28	2004	Wood, Louise, et..al, Drug Safety, "The General Practice Research Database Role in Pharmacovigilance;" 27 (12): pp. 871 881, (2004)	

Exh No.	Date	Description	Defendants' Objections
1133.29	2004	Goldman, Stephen A., Drug Safety, "Communication of Medical Product Risk- How Effective is Effective Enough?", 27(8), pp. 519 - 534, (2004)	
1133.30	2005	Umrath, Thomas, et. al, Drug Information Journal, "Establishing an AdverseEvent Collection Team in a Pharmaceutical Company Safety Department: Impact on Report Quality and Customer Satisfaction," Vol. 39, pp. 81-88, (2005)	
1133.31	2005	Almenoff, June, et. al, Drug Safety, "Perspectives on the Use of Data Mining in Pharmacovigilance", 28(11), pp. 981 --1007, (2005)	
1133.32	2005	Umrath, Thomas, et. al, Drug Information journal, "Establishing an Adverse Event Collection Team in a Pharmaceutical Company Safety Department: Impact on Report Quality and Customer Satisfaction," Vol. 39 pp. 81-88, (2005)	
1133.33	2005	Almenoff; June, et. al, Drug Safety, "Perspectives on the Use of Data Mining in Pharmacovigilance", 28(11}, pp_ 981 - 1007, (2005)	
1133.34	2005	U.S Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Centel for Biologics Evaluation and Research (CBER) ICH, "Guidance for Industry - E2E Pharmacovigilance Planning", pp. 1 - 18, (2005)	
1133.35	2005	U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Center for Biologies Evaluation and Research (CHER) Clinical Medical "Guidancefor Industry -"Good Pharmacovigilance Practices and Pharmacoepidemiologie Assessment", pp. 1 - 20, (2005)	
1133.36	2006	Hauben, Manfred, et. al, Drug Safety, "What Counts in Data Mining," 29 (10): pp. 827- 832, (2006)	

Exh No.	Date	Description	Defendants' Objections
1133.37	2006	Almenoff, June S., et. at, Drug Safety, "Comparative Performance of Two Quantitative Safety Signaling Methods Implications for Use in a Pharmacovigilance Department," 29 (10): pp. 875 - 887, (2006)	
1133.38	2006	Ridley, David B., et, al, Health Affairs The Policy Journal of the Health Sphere, "Spending on Postapproval Drug Safety", 25, No. 2, doi:10.1377/hlthaff.2.2.429, pp. 429 - 436,(2006)	
1133.39	2006	Hartford, Craig G., et. al, Drug Safety, "Pharmacovigilance during the Pre-Approval Phases - An Evolving Pharmaceutical Industry Model In Response To ICH E2E, CIOMS VI, FDA AND EMEA/CHMP Risk-Management Guidelines", 29(8), pp 657 673, (2006)	
1133.40	2006	Hauben, Manfred, et. al, Drug Safety, "What Counts in Data Mining," 29 (10): pp. 827'- 832, (2006)	
1133.41	2006	Hauben, Manfred; et al, Drug Safety, "Extension of Points on Clarifying Terminology in Drug Safety," 29 (3): pp. 273-275 (2006)	
1133.42	2007	Matsushita, Yasuyuki, et. al, Drug Safety, "Criteria Revision and Performance Comparison of Three Methods of Signal Detection Applied to the Spontaneous Reporting Database of a Pharmaceutical Manufacturer," 30 (8): 715-726, (2007)	
1133.43	2008	Leone, Roberto, et.: al, Drug Safety, "Drug-Related Deaths -An Analysis of the Italian Spontaneous Reporting Database", 31(8), pp. 703 - 713, (2008)	
1133.44	2009	Edwards, I. Ralph, et. at, Drug Safety, "Understanding and Communicating Key Concepts in Risk-Management", 32(6), pp. 449 - 452, (2009)	
1133.45	2009	Hauben, Manfred, et. al, Drug Safety, "Defining 'Signal' and its Subtypes in Pharmacovigilance Based on a Systematic Review of Previous Defnitions", 32(2), 99-110, (2009)	

Exh No.	Date	Description	Defendants' Objections
1133.46	2009	Hauben, Manfred, et. al, Drug Safety, "An Evaluation of Three Signal-Detection Algorithms Using a Highly Inclusive Reference Event Database", 32(6), pp 509 - 525, (2009)	
1136.1	1979	Kramer, M. S., et. al, <u>JAMA</u> , "An Algorithm for the Operational Assessment of Adverse Drug Reactions - Background, Description, and Instructions for Use", Vol 242, No. 7, pages 623 -- 632; (1979)	
1136.2	1979	Hutchinson, MB, et. al, <u>JAMA</u> , "An Algorithm for the Operational Assessment of Adverse Drug Reactions - Demonstration of Reproducibility and Validity", Vol 242, No. 7, pages 633 - 638, (1979)	
1136.3	1979	Leventhal, J. M, et. at, <u>JAMA</u> , "An Algorithm for the Operational Assessment of Adverse Drug Reactions - Results of Tests Among Clinicians", Vol 242, No. 18, pages 1991--1994, (1979)	
1136.4	1981	Naranjo, C. A., et. al, <u>Clinical Pharmacology Ther.</u> August, "A method for estimating the probability of adverse drug reactions", Volume 30, Number 2, pp. 239 -- 45, (1981)	
1136.5	1982	Jones, J. K, <u>Family & Community Health / August</u> , "Adverse drug reactions in the community health setting: approaches to recognizing, counseling, and reporting", pp. 58 - 67, (1982)	
1136.6	1984	Turner, W. M, PharmD, <u>Drug Information Journal</u> , "The Food and Drug Algorithm Special Workshop - Regulatory", Vol. 18, pp. 259-266, (1984)	
1136.7	1985	Kramer, M.S., et. al, <u>The Journal of Pediatrics</u> , "Adverse drug reactions inGeneral pediatric outpatients", 106:305 - 310, (1985)	
1136.8	1986	Michel, D. J., et. al, <u>American Journal of Hospital Pharmacy</u> , "Comparison three algorithms used to evaluate adverse drug reactions", Vol 43, pp. 1709 - 1714, (1986)	
1136.9	1989	Stern, R. S., <u>Seminars in Dermatology</u> "Epidemiologic Assessment of Adverse Drug Effects", Vol 8, No 3, pp 136 - 140, (1989)	

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1136.10	1990	Edwards, I. R., et. al, <u>Lancet</u> , "Quality criteria for early signals of possible Adverse drug reactions", 336: 156 - 58, (1990)	
1136.11	2005	Strom, B. L., <u>Pharmacoepidemiology 4th Edition</u> , "Study Designs Available for Pharmacoepidemiology Studies", Chapter 2, pages 17 - 28, (2005)	
1136.12	2007	Moye, Lemuel A. M.D., Ph.D., " <u>Expert Report</u> ", pages 1 - - 96, Appendix A References pages 1 - 6, Appendix B - CV pages 1 - 25, Appendix C - Case Reports and Causality", pages 1 - 10, (2007)	
1136.13	2007	Hauben, M., et. al, <u>Drug Safety</u> , "Gold Standards in Pharmacovigilance The Use of Definitive Anecdotal Reports of Adverse Drug Reactions as Pure Gold and High-Grade Ore", 30 (8): 645 - 655, (2007)	
1136.14	2007	Kelly, W. N., et. al, <u>Drug Safety</u> , "Guidelines for Submitting Adverse Event Reports for Publication", 30 (5): 367 - 373, (2007)	
1136.15	2007	Perrio, M., et. al, <u>Drug Safety</u> , "Application of the Bradford Hill Criteria To Assess the Causality of Cisapride-Induced Arrhythmia. A Model for Assessing Causal Association in Pharmacovigilance", 30 (4) 333 - 346, (2007)	
1136.16	2008	Aronson, J. K, <u>Drug Safety</u> , "Publishing Histories of Adverse Reactions to Medicaments Anecdotally, The PHARMA guidelines for Reporting Suspected Adverse Drug Reactions", 31 (4), page 355 - 356, (2008)	
1136.17	2008	Agbabiaka, T.B, et. al, <u>Drug Safety</u> , "Methods for Causality Assessment of Adverse Drug Reactions A Systematic Review", 31 (1): 21 - 37, (2008)	
1137.1	No date	GENERAL OUTLINE. OF CONTENTS - 01/232 .TO '03/232	Lacks authentication (Rule 901)
1137.2	No date	DETAILED TABLE ON-CONTENTS - 04 /232 TO ,16/232	Lacks authentication (Rule 901)
1137.3	No date	PART I - GUIDELINES FOR MARKETING AUTHORISATION HOLDERS – 17/232 TO 106/232	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
1137.4	No date	PART II - GUIDELINES FOR COMPETENT AND THE AGENCY - 107/232 TO 155/232	Lacks authentication (Rule 901)
1137.5	No date	PART III ELECTRONIC EXCHANGE OF PHARMACOVIGILANCE INFORMATION IN-THE.EU - 156/232; TO 180/232	Lacks authentication (Rule 901)
1137.6	No date	PART IV - COMPETENT AUTHORITIES ON PHARMACOVIGILANCE COMMUNICATION - 181/232 TO 191/232	Lacks authentication (Rule 901)
1137.7	No date	ANNEXES 192/232 To 232/232	Lacks authentication (Rule 901)
1138-1138.10		Comparable Safety of Antipyretics and Analgesics with respect to skin reactions and liver toxicity	Lacks authentication (Rule 901)
1139.1-1139.9		WHO Rejection of ibuprofen To Essential List of Medicines, 2001 & 2005 & related documents	Lacks authentication (Rule 901)
1139.1	2002	Ibuprofen (WHO) Unicef.org. RE: Pediatric ibuprofen for Essential Medicines List December-2002	Lacks authentication (Rule 901)
1139.2	2002	Application for inclusion of pediatric ibuprofen on WHO Essential Medicines List December-2002	Lacks authentication (Rule 901)
1139.3	2002	Application for Pediatric ibuprofen formulations to be added to the WHO Model List of Essential Medicines, review of applications by Expert Committee Member December (2002)	Lacks authentication (Rule 901)
1139.4	2002	Ibuprofen Liquid formulations for treating fever in children Pain Relief Unit, Churchill Hospital Headington, Oxford, December (2002)	Lacks authentication (Rule 901)
1139.5	2003	EML-WHO/Essential Medicines, WHO Model List (revised April 2003)	Lacks authentication (Rule 901)
1139.6	2004	World Health Organization Technical Report Series; The Selection and Use of Essential Medicines; (2004)	Lacks authentication (Rule 901)
1139.7	2006	World Health Organization Technical Report Series; The Selection and Use of Essential Medicines; (2006)	Lacks authentication (Rule 901)
1139.8	No date	WHO.INT, <u>Essential Drugs and Medicines Policy</u> , "The Rationale of Essential Medicines" World Health Organization	Lacks authentication (Rule 901)
1139.9	No date	EML-WHO/EDM Essential Medicines Library, Medicine link page, ibuprofen WHO Model List of Essential Medicines in alphabetical order	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
1149	No date	Ibuprofen Industry Association materials	Lacks authentication (Rule 901)
1150	No date	EMEA Revision to NSAID labeling	Lacks authentication (Rule 901)
1151	No date	FDA Memorandum on NSAID labeling	Lacks authentication (Rule 901)
1152-1160	2006	2/27/06 FDA Provigil Memorandum Provigil Memorandum and related documents by Cephalon, by FDA and FDA Psychopharmacology Committee (See Exs. 513.1-513.5)	Lacks authentication (Rule 901)
1153	2006	3/23/06 Summary Minutes of the Psychopharmacologic Drugs Advisory Committee	Lacks authentication (Rule 901)
1154	2006	FDA Medical Office Reviewer Memorandum of Provigil and Serous Skin Reaction	Lacks authentication (Rule 901)
1155	2006	3/23/06 Psychopharmacologic Drugs Advisory Committee (PDAC) Meetin Transcript	Lacks authentication (Rule 901)
1156	2007	FDA Drug Safety Newsletter Volume 1, NO. 1 - Safety Alert on Provigil and SJS/TEN	Lacks authentication (Rule 901)
1157	2007	Medical Officer Review Of Sparlon's SNDA for Provigil; and Advisory Committee's decision, 2006-2007	Lacks authentication (Rule 901)
1158	No date	FDA Provigil Memorandum and related documents by Sponsor, by FDA and FDA Psychopharmacology Committee	Lacks authentication (Rule 901)
1159	No date	FDA Provigil Memorandum and related documents by Sponsor, by FDA and FDA Psychopharmacology Committee	Lacks authentication (Rule 901)
1160	No date	FDA Provigil Memorandum and related documents by Sponsor, by FDA and FDA Psychopharmacology Committee	Lacks authentication (Rule 901)
1161	2002	Tentative Final Monograph (McNeil's NDAs, Wyeth's NDAs, Federal Register for 200 mg Ibuprofen, and related materials; 67 FR 162, 9/21/2002	
1162	2006	Tentative Final Monograph (McNeil's NDAs, Wyeth's NDAs, Federal Register for 200 mg Ibuprofen, and related materials; 71 FR 247, 12/26/06	

Exh No.	Date	Description	Defendants' Objections
1163	2006	Tentative Final Monograph (McNeil's NDAs, Wyeth's NDAs, Federal Register for 200 mg Ibuprofen, and related materials; FDA Campaign on Safe Use of Analgesics and Antipyretics 4/2006	
1164	2009	Tentative Final Monograph (McNeil's NDAs, Wyeth's NDAs, Federal Register for 200 mg Ibuprofen, and related materials; 74 FR 81, 4/28/09	
1165	No date	Tentative Final Monograph (McNeil's NDAs, Wyeth's NDAs, Federal Register for 200 mg Ibuprofen, and related materials;	Lacks authentication (Rule 901)
1166	No date	Tentative Final Monograph (McNeil's NDAs, Wyeth's NDAs, Federal Register for 200 mg Ibuprofen, and related materials;	Lacks authentication (Rule 901)
1167	No date	Tentative Final Monograph (McNeil's NDAs, Wyeth's NDAs, Federal Register for 200 mg Ibuprofen, and related materials;	Lacks authentication (Rule 901)
1168	No date	Tentative Final Monograph (McNeil's NDAs, Wyeth's NDAs, Federal Register for 200 mg Ibuprofen, and related materials;	Lacks authentication (Rule 901)
1169	No date	Tentative Final Monograph (McNeil's NDAs, Wyeth's NDAs, Federal Register for 200 mg Ibuprofen, and related materials;	Lacks authentication (Rule 901)
1170	No date	Tentative Final Monograph (McNeil's NDAs, Wyeth's NDAs, Federal Register for 200 mg Ibuprofen, and related materials;	Lacks authentication (Rule 901)
1171-1190		FDA regulations, 201.66, 202.1, 201, 314.26, 314.50, 201.56, 201.57, 314.70, 314.80, 314,81, 314,81, and IND regulations	
1228	5.6.09	Deposition of Richard Vezina and accompanying Exhibits	
1229	1.14.08	Deposition of Sam Lesko and accompanying Exhibits	
1299.1	10.19.99	McNeil Form 483 Inspection Reports (incorrectly dated January 10, 1999, in Dr. Tackett's Report)	Lacks authentication (Rule 901)
1299.2	6.7.04	As described in paragraph 130.7[1] of Dr. Randall Tackett's Report	
1299.3	1.12.06	As described in paragraph 130.7[1] of Dr. Randall Tackett's Report	
1299.4	2.19.08	As described in paragraph 130.7[1] of Dr. Randall Tackett's Report	

Exh No.	Date	Description	Defendants' Objections
1299.5	6.4.09	As described in paragraph 130.7[1] of Dr. Randall Tackett's Report	
1299.6	1.8.10	As described in paragraph 130.7[1] of Dr. Randall Tackett's Report	
1299.7	4.30.10	As described in paragraph 130.7[1] of Dr. Randall Tackett's Report	
1230		Lazarou J, Pomeranz BH, Corey PN. "Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies," <i>JAMA</i> . 1998;279:1200-1205	
1231	2006	Furberg, CD, et al., "The FDA and Drug Safety: A Proposal for Sweeping Changes, Arch Intern Med. 2006;166:pp. 1938-1942	
1232	2007	FDA's Drug Safety Newsletter (Vol. 1, Issue 1, Fall 2007	
1233	2008	FDA's Drug Safety Newsletter (Vol 1, Issue 2, Winter 2008);	
1234	2008	FDA's Drug Safety Newsletter (Vol 1, Issue 3, Spring 2008);	
1235	2008	FDA's Drug Safety Newsletter (Vol 1, Issue 4, Summer 2008);	
1236	2005	Pfizer Briefing to Health Canada on Bextra Submission, June 2005	Lacks authentication (Rule 901)
1237.1 & 1237.2		Table of Drugs withdrawn from the market with no formal epidemiological proof of causation and FDA List of All Withdrawn Drugs	Lacks authentication (Rule 901)
1238	2005	Letko, et al., Ann Allergy Asthma Immunol. 2005;94:419-436	
1239	1990	Roujeau, JC, J AM ACAD DERMATOL 1990;23:1039-58.	
1297	2006	Hazell, et al., Drug Safety 2006; 29 (5): 385-396, 2006	
1298		Hepatotoxicity of Ibuprofen Literature and WHO Hepatotoxicity Folder	Lacks authentication (Rule 901)
1299	2/10/1992, 4/30 & 5/06/1993 & 10/15/2003	McNeil-483s Folder, FDA 483 Citation to McNeil-with letter	Lacks authentication (Rule 901)
1299.1	10/19/1999, 11/17/1999	FDA 483 Citation to McNeil-PV and Legal Dept. -with Letter	Lacks authentication (Rule 901)
1299.2	1/4/2006	FDA 483 Citation to McNeil-with letter	Lacks authentication (Rule 901)
1299.3	5/17/2004	FDA 483 Citation to McNeil-with letter	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
1299.4	2/19/2008	FDA 483 Citation to McNeil-with letter	Lacks authentication (Rule 901)
1299.5	7/31/2008	FDA 483 citation with letter to McNeil	Lacks authentication (Rule 901)
1299.6	8/6/2008	FDA 483 citation with letter to McNeil	Lacks authentication (Rule 901)
1299.7	5/19/2009	FDA 483 Citation to McNeil with letter	Lacks authentication (Rule 901)
1299.8	1/8/2010	FDA 483 Citation to McNeil with letter	Lacks authentication (Rule 901)
1299.9	7/9/2010	FDA 483 Citation to J&j/Merck consumer with letter	Lacks authentication (Rule 901)
1299.1	4/30/2010	FDA 483 Citation to McNeil with letter	Lacks authentication (Rule 901)
1300		FDA Warning Letter to J&J, Congressional Testimony-Recall Folder-Dear Healthcare Letter;	Lacks authentication (Rule 901)
1300.1	1/3/2006	Dear Health Care Professional Letter by McNeil on Pancrease	Lacks authentication (Rule 901)
1300.2	5/14/2010	Dear health Care Professional Letter by McNeil on Recall	Lacks authentication (Rule 901)
1300.3	12/1/2008	Letter-Editor by Celgene Scientists re: Risk of SJS TEN from Lenalidomide	Lacks authentication (Rule 901)
1300.4	Aug-09	Dear Healthcare Professional Letter by Tibotec for risk of serious skin reactions, SJS-TEN	Lacks authentication (Rule 901)
1300.5	Apr-09	Dear Healthcare Professional Letter by Genentech for risk of serious skin reactions, SJS-TEN	Lacks authentication (Rule 901)
1300.6	12/13/2002	1st Dear Healthcare Professsional Letter by Pfizer regarding risk of SJS and TEN with Bextra	Lacks authentication (Rule 901)
1300.7	Nov-04	2nd Dear Healthcare Professsional Letter by Pfizer regarding risk fo SJS and TEN with Bextra	Lacks authentication (Rule 901)
1300.8	2010	Dear Doctor Letter re Recall dtd May 14, 2010 from McNeil	Lacks authentication (Rule 901)
1300.9	1993	March 26, 1993, McNeil Dear Doctor Letter re change name from Pediaaprofen to CM	Lacks authentication (Rule 901)
1300.10	1984	June 6, 1984, McNeil Dear Healthcare Writer Letter re Choice in Analgesics re OTC Switch	Lacks authentication (Rule 901)
1301-1385		Mechanisms of Rash \ SJS \ TEN \ DRESS (Pharmacology and Toxicology) Molecular and Immunological Causation	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
1301.1		Written Congressional Testimony of Colleen A., Coggins, Worldwide Chairman, Consumer Group, Johnson & Johnson before the Committee on Oversight and Government Reform, U.S. House of Representatives, May 27, 2010	
1400	2003	US and EU patents Relating to Dexibuprofen - 4/22/03	Lacks authentication (Rule 901)
1401	No date	US and EU patents Relating to Dexibuprofen - 9/19/07	Lacks authentication (Rule 901)
1402	1991	US and EU patents Relating to Dexibuprofen - 12/24/91	Lacks authentication (Rule 901)
1403	1993	US and EU patents Relating to Dexibuprofen - 7/19/93	Lacks authentication (Rule 901)
1404	1993	US and EU patents Relating to Dexibuprofen - 10/15/1993	Lacks authentication (Rule 901)
1405	2008	US and EU patents Relating to Dexibuprofen - 5/15/08	Lacks authentication (Rule 901)
1406	2005	Roujeau, JC, Toxicology, "Clinical Heterogeneity of drug hypersensitivity," Vol. 209; pp. 123-129, (2005)	
1407	2003	Roujeau, JC, et al., Am J Clin Dermatol., "Differential Diagnosis of Severe Cutaneous Drug Eruptions," Vol. 4(8); pp. 561-572, (2003)	
1411	2009	Department of Health and Human Services, Food and Drug Administration Office of Device Evaluation, Letter to John Podesta of 1.7.09 President Barack H. Obama, 4/2/09	
		SCIENTIFIC LITERATURE ON THE RELATIONSHIP OF IBUPROFEN TO SJS AND TEN	
2001	1978	Sternlieb P., et al., NY State Jour of Med, "Stevens-Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen", pp. 1239-43, 1239 & 1240 (1978)	
2002	1984	Wintroub B., Current Perspectives in Immunodermatology, "Cutaneous Drug Reactions", pp. 84-97, (1984)	
2003	1984	Stern R., et al., JAMA "An Expanded Profile of Cutaneous Reactions to Nonsteroidal Anti-inflammatory Drugs", Vol. 252, No. 11, pp. 1433-7, (Sept. 1984).	

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2004	1985	Hurwitz, R, et al., J Am Acad Dermatol, "Toxic shock syndrome or toxic epidermal necrolysis?", 7:246-254, 251 (1982)	
2005	1985	O'Brien W., et al., Jour of Rheumatology, "Rare Adverse Reactions to Nonsteroidal Antiinflammatory Drugs," Vol. 12, No. 1, pp. 13-17, 15 (1985)	
2006	1985	Bigby M., et al., Jour of Amer Acad Derma, "Cutaneous Reactions to Nonsteroidal Anti-Inflammatory Drugs," Vol. 12, No. 5, Part 1, pp. 866-75, 871 (1985).	
2007	1987	Roujeau J., Scand J Rheumatology, "Clinical Aspects of Skin Reactions to NSAIDs," Suppl. 65, pp. 131-4, 131 & 133, table I (1987).	
2008	1987	"The Culprit Drugs in 87 Cases of Toxic Epidermal Necrolysis (Lyell's Syndrome)," by Jean-Claude Guillaume, et al. Published in <i>Arch Dermatol</i> , Vol. 123, pp. 1166-70 (September 1987).	
2009	1987	Stern, R and Wintroub, B., Adv Dermatol, "Adverse Drug Reactions: Reporting and Evaluating Cutaneous Reactions," 2:3-17 (1987).	
2010	1987	Roujeau J., et al., Scand J Rheumatology, "Clinical Aspects of Skin Reactions to NSAIDs", Sup. 65, pp. 131-4, (1987).	
2011	1988	Laing V., et al., J Am Acad Dermatol, "Pemphigoid-Like Bullous Eruption Related to Ibuprofen", Vol. 19, pp. 91-4, (1988)	
2012	1989	Stern, R, et al, Pharmacol Skin, "Adverse Cutaneous Reactions to Nonsteroidal Anti-Inflammatory Drugs", Vol 2, pp 148-156, 151(1989).	
2013	1989	Stern R., et al., <u>Jour of the Amer Academy of Dermatology</u> , "Usefulness of Case Report Literature in Determining Drugs Responsible for Toxic Epidennal Necrolysis", Vol. 21,. No.2, Part 1, pp. 317-22,a (1989).	
2014	1989	Bigby M., et. al., Primary Care, "Allergic Cutaneous Reactions to Drugs," Vol. 16, No. 3, (1989)	

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2015	1990	Roujeau J., et al., Jour of the Amer Academy of Dermatol, "Continuing Medical Education: Toxic Epidermal Necrolysis (Lyell Syndrome)," Vol. 23, No. 6, pp. 1039-58,1047 (1990).	
2016	1990	"Toxic Epidermal Necrolysis (Lyell Syndrome), Incidence and Drug Etiology in France, 1981-1985," by Jean-Claude Roujeau, et al. Published in <i>Arch Dermatol</i> , Vol. 126, pp. 37-42 (January 1990).	
2017	1991	Strom B., et al., <u>Statistics in Medicine</u> , "Using A Claims Database to Investigate Drug-Induced Stevens-Johnson Syndrome", Vol. 10, pp. 566-76, (1991).	
2018	1991	Strom B., et al., <u>Arch Dermatol</u> , "A Population-Based Study of Stevens-Johnson Syndrome", Vol. 127, pp. 831-8, (June 1991).	
2019	1992	Parsons J., et al., International Jour of Dermatol, "Toxic Epidermal Necrolysis," Vol. 31, No. 11, pp. 749-68, 750 (1992).	
2020	1993	Halpern S., et al., Adverse Drug React Toxicol Rev, "Ibuprofen Toxicity A Review of Adverse Reactions and Overdose," Vol. 12, No. 2, pp. 107-28, see, "Skin reactions" on p. 5 (1993).	
2021	1994	Halpern S., et al., et al., Arch Dermatology, "Cutaneous Toxicity of Ibuprofen", Vol. 130, February, pp. 259-260, (1994).	
2022	1994	Roujeau J., et al., New England Jour of Med, "Severe Adverse Cutaneous Reactions to Drugs," Vol. 331, No. 19, pp. 1272-85, 1272 & 1279, table 4 (1994).	
2023	1995	Roujeau J., et al., New England Jour of Med, "Medication Use and the Risk of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis," Vol. 333, No. 24, pp. 1600-7, 1606(1995).	
2024	1995	Power W., et al., Ophthalmology, "Analysis of the Acute Ophthalmic Manifestations of the Erythema Multiforme/Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis Disease Spectrum," Vol. 102, No. 11, pp. 1669-76, 1672 (1995).	

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2025	1995	Lesko S., et al., JAMA, "An Assessment of the Safety of Pediatric Ibuprofen," Vol. 273, No. 12, pp. 929-33, (1995).	
2026	1996	Alam I., et al., Amer Jour of Gastroenterology, "Vanishing Bile Duct Syndrome Temporally Associated with Ibuprofen Use," Vol. 91, No. 8, pp. 1626-30, 1626 (1996).	
2027	1997	Salomon D., et al., Annales De Dermatologie et de Venereologie, "Five Cases of Toxic Epidermal Necrolysis Treated by Intravenous Immunoglobulins with Favorable Results," pp. S216-7, (1997).	
2028	1997	Lebargy, F, Intensive Care Med, "Pulmonary complications in toxic epidermal necrolysis: a prospective clinical study", (1997) 23: 1237-1244, 1239, table 1 (1997).	
2029	1997	Mockenhaupt, M., et al., Abstracts from the 1997 Annual Meeting International Dermatol Epidemiology Association, Abstract 28, "Risk Factors for Stevens-Johnson Syndrome(SJS) and Toxic Epidermal Necrolysis (TEN) Evaluation of Non-Steroidal Antiinflammatory Drugs (NSAIDS) and Muscle Relaxants," Vol. 108, No. 3, p. 367, 1997.	
2030	1998	Wolkenstein, et al, Clinics in Dermatology, "Drug – Induced Toxic Epidermal Necrolysis", Vol 16, pp 399-409, 403 (1998)	
2031	1998	Viard, I, et al, Amer Assoc Advancement Science, "Inhibition of Toxic Epidermal Necrolysis by Blockade of CD95 with Human Intravenous Immunoglobulin", Vol 282, pp 490 – 493, 491 (1998).	
2032	1998	Srivastava, M, et al, Gastroenterology 1998, "Drug-Associated Acute – Onset Vanishing Bile Duct and Stevens-Johnson Syndrome in a Child", Vol 115, pp. 743-746, 743 (1998).	
2033	1999	Fritsch, P, et al, Fitzpatrick's Dermatology in General Medicine Fifth Edition, "Stevens-Johnson Syndrome – Toxic Epidermal Necrolysis", Vol I, Chapter 59, pp. 644 – 654, 645 (1999).	

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2034	1999	Sheridan R., et al, Jour of Burn Care & Rehab, "A Management of Severe Toxic Epidermal Necrolysis in Children," pp. 497-500, 498, table 1 (1999).	
2035	2000	Garcia-Doval, I, Arch Dermatol, "Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome", Vol 136, pp. 323-327, 323 & 325, table 2 (March, 2000).	
2036	2000	Wolkenstein, P., et al., <u>Dermatologic Clinics</u> , "Toxic Epidermal Necrolysis", Vol. 18, No.3, pp. 485-95, (July 2000).	
2037	2000	Stern, R., Arch Dermatol, "Improving the Outcome of Patients With Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome," Vol. 136 (March 2000).	
2038	2000	"European Study of Serious Cutaneous Adverse Reactions, Instruction Manual," Version 3. Dated: March 2000.	
2039	2000	Mockenhaupt M., et al., "Antirheumatic Medication and the Risk for Severe Cutaneous Adverse Reactions (SCAR)," Date: August 2000. (ISPE)(Bates# DEX-000295 to DEX-000303)	
2040	2001	Spies M., et al., Amer Academy of Pedia, "Treatment of Extensive Toxic Epidermal Necrolysis in Children," Vol. 108, pp. 1162-8, 1164, table 1 (November, 2001).	
2041	2001	Morelli M., et al., Digestive Diseases & Sciences, "Stevens-Johnson Syndrome and Cholestatic Hepatitis," Vol. 46, No. 11, pp. 2385-8, 2387 & 2388 (November, 2001)	
2042	2002	Sheridan, R., et al, Pediatrics 2002, "Long Term Consequences of Toxic Epidermal Necrolysis in Children," pp. 109: 74-78, 75 (2002)	
2043	2002	Rothman, Kenneth J.. Epidemiology: An Introduction. New York: Oxford University Press, USA, 2002.	
2044	2003	Bachot N., et al. & Roujeau JC. Arch Dermatol "Intravenous Immunoglobulin Treatment for Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: a prospective noncomparative study showing no benefit on mortality or progression" 139: 33-36, 34 (2003)	

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2045	2003	Mockenhaupt M., et al., The Journal of Rheumatology, "The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Antiinflammatory Drugs: A Multinational Perspective," pp. 2234-40, 2236, table 1 and 2239 (2003)	
2046	2003	Prins C., et al. Dermatology, "Effect of High Dose Immunoglobulin Therapy in Stevens-Johnson Syndrome: A Retrospective, Multicenter Study" 207: 96-99, 97 (2003)	
2047	2003	Prins C., et al., Arch Dermatol, "Treatment of Toxic Epidermal Necrolysis with High-Dose Intravenous Immunoglobulins" 139: 26-32, 28 & 29 (2003)	
2048	2003	Roujeau, J., et al., Arch Dermatol, "Intravenous Immunoglobulin Treatment for Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis," Vol. 139, No. 1, pp. 33-36, 2003.	
2049	2003	Mockenhaupt, et al., The Journal of Rheumatology, "The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Antiinflammatory Drugs: A Multinational Perspective", Vol. 30, No. 10, (2003)	
2050	2004	Taghian M., et al., Jour of Pediatrics, "Acute Vanishing Vile Duct Syndrome After Ibuprofen Therapy in a Child," pp. 273-6, 273 & 275 (2004).	
2051	2005	Kim JK., et al., Acta Dermatol Venereol, "Toxic Epidermal Necrolysis: Analsysis of Clinical Course and SCORTEN-based Comparison of Mortality Rate and Treatment Modalities for Korean Patients" 85: 497-502, 498 (2005)	
2052	2005	Paquet, P., et. al., J Oral Pathol Med, "Cystic lesion of the parotid following drug-induced toxic epidermal necrolysis (Lyell's syndrome)", 34: 380-2, 380 (2005).	
2053	2005	Di Pascuale, et al & Tseng, Opthamology, "Correlation of corneal complications with eyelid cicatricial pathologies in Tiffanys with Steven Johnson syndrome and toxic epidermal necrolysis syndrome." 112:904-912, (2005)	

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2054	2005	Haber, J., et al., J Burn Care, "Late Outcomes in Adult Survivors of Toxic Epidermal Necrolysis After Treatment in a Burn Center,". Vol. 26, pp. 33-41, (2005)	
2055	2007	Neuman, M., et. al., Translational Research, "Apoptosis in ibuprofen-induced Stevens-Johnson syndrome", 149:254-259, 255, 256 & 258 (2007).	
2056	2007	Dore, J. & Salisbury, R., J Burn Care Res, "Morbidity and Mortality of Mucocutaneous Diseases in the Pediatric Population at a Tertiary Care Center", 28:865-870, 865 (2007).	
2057	2007	Mockenhaupt, M., et. al., Journal of Investigative Dermatology advanced online publications, "Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: Assessment of Medication Risks with Emphasis on Recently Marketed drugs", The EuroSCAR-Study", doi:10.1038/sj.jid.5701033, 41 & 42 (2007).	
2058	2007	Sidoroff, A., et al., "Risk factors for acute generalized exanthematous pustulosis (AGEP) – results of a multinational case-control study (EuroSCAR)," Published in British Journal of Dermatology 2007.	
2059	2008	Raksha, M. Patel, et al, Indian J Dermatol Venereology Leprology, "Clinical study of cutaneous drug eruptions in 200 patients", 74:80, 1 & 2 (2008)	
2060	2008	Sharma VK, et. al., Indian J. Dermatol Venereol Leprol, "Stevens Johnson syndrome, toxic epidermal necrolysis (TEN) and SJS-TEN overlap: A retrospective study of causative drugs and clinical outcome", 74:238-40, 238 & 239, table 1 (2008).	
2061	2008	Yun, Sook Jung, et. al., Department of Dermatology, Chonnam National University Medical School, and Clinical Trial Center, Chonnam National University Hospital, "Serum Lactate Dehydrogenase Is A Novel Marker for the Evaluation of Disease Severity in the Early Stage of Toxic Epidermal Necrolysis", 217:254-259, DOI: 10.1159/000148255, (2008).	

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2062	2008	Gresik, C., ... Gamelli, R., et al., J. Burn Care & Research, "Ecthyma Gangrenosum Following Toxic Epidermal Necrolysis Syndrome in a 3-Year-Old Boy-a Survivable Series of Events" pp. 555-558, 557 (2008)	
2063	2008	Khopkar, U. Editor, et. al, Indian Journal of Dermatology Venereology & Leprology, Table of Contents, Vol 74, Issue 1, Jan – Feb (2008)	
2064	2008	Schneck, J., et al., "Effects of treatments on the mortality of Stevens-Johnson syndrome and toxic epidermal necrolysis: A retrospective study on patients included in the prospective EuroSCAR Study," Published in J. Am. Acad. Dermatol., Vol. 58, No. 1, Date: January 2008.	
2065	2009	Levi, et al., Pediatrics, "Medications as Risk Factors of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Children: A Pooled Analysis", 123:2;e297-e304 e297 and e300, table 3 (2009).	
2066	2009	Yang Y. Xu J. Li F. Zhu X. Combination therapy of intravenous immunoglobulin and corticosteroid in the treatment of toxic epidermal necrolysis and Stevens-Johnson syndrome: a retrospective comparative study in China. Internatl J Dermatol. 2009; 48: 1122-1128.	
2067	2009	Rijal A., et al., Indian J Dermatol Venereol Leprol "Outcome of Stevens Johnson syndrome and toxic epidermal necrolysis treated with corticosteroids" 75: 613-614, 613 (2009).	
2068	5/9/1998	David S. Becker, "Toxic Epidermal Necrolysis," <i>The Lancet</i> , Vol. 351, pp. 1417-20 (May 9, 1998).	
2069	11/7/2000	Email to R. Stern and copied to Maja Mockenhaupt regarding status of funding for research. Dated November 7, 2000. DEX000286.	
2070	9/14/2001	Fax to Rob regarding comments on a recent draft concerning NSAIDS and SCAR. September 14th, 2001. DEX000208-217.	

Exh No.	Date	Description	Defendants' Objections
2071	4/3/2002	Unproofed Draft of April 3, 2002, "The Risk of Stevens-Johnson Syndrome and toxic epidermal necrolysis Associated with nonsteroidal anti-inflammatory drugs. A Multinational Perspective," by Mockenhaupt M, Parsells J, et al.	
2072	9/11/2004	"Epidemiology and Drug Risks of Severe Cutaneous Adverse Drug Reactions (ADR) in Europe," by Mockenhaupt M, et al. from the 34th Annual European Society for Dermatological Research (ESDR) Meeting, September 11, 2004 in Vienna, Austria.	
2073	No Date	Power Point slides for "Nosology and treatment of Stevens-Johnson syndrome and toxic epidermal necrolysis," by Maja Mockenhaupt.	Lacks authentication (Rule 901)
2074	No Date	OrphaNews Europe Newsletter of the Rare Diseases Task Force, "Interview Dr. Maja Mockenhaupt, RegiSCAR." No date.	
		WHAT CAUSES SJS/TEN	
2100	1987	Roujeau, JC, "Clinical Aspects of Skin Reactions to NSAIDs" J. Rheum., (Suppl. 65) 131-134, 132 (1987)	
2101	1990	Roujeau, JC, "Toxic Epidermal Necrolysis (Lyell syndrome): Review," J Amer Acad Dermatol., 23(6), part 1:1039-1061, pp. 1039 & 1046 (1990)	
2102	1990	Roujeau, JC, "Toxic Epidermal Necrolysis (Lyell syndrome)" Arch. Dermatol., 126:37-42, 41 (1990)	
2103	1993	Bastuji-Garin, Rzany, Stern, et. al., Archives of Dermatology, "Clinical Classification of Cases of Toxic Epidermal Necrolysis, Stevens-Johnson syndrome, and Erythema Multiforme, Vol. 129, 92-96, 92 (1993)	
2104	1993	Correia, O, et al., "Evolving Pattern of Drug-Induced Toxic Epidermal Necrolysis," Dermatology, 186:32-57, 32 (1993)	
2105	1994	Roujeau, et. al. "Severe Cutaneous Reactions to Drugs, NEJM, Vol. 331, No. 19, 1271-1285, 1273 (1994)	

Exh No.	Date	Description	Defendants' Objections
2106	1995	Assier, Bastuji-Garin, Revuz & Roujeau, "Erythema Multiforme With Mucous Membrane Involvement and Stevens-Johnson Syndrome Are Clinically Different Disorders With Distinct Causes", Arch. Dermatol., 131:539-543, 543 (1995)	
2107	1997	Roujeau, JC, Rev. Rheum. [Engl. Ed.], "Severe Drug-Induced Blistering Disorders," Vol. 64 (1); pp. 5-9, 7 (1997)	
2108	1997	Roujeau, JC, Journal of Dermatology, "Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis are Severity Variants of the Same Disease which differs from Erythema Multiforme," Vol. 24; pp. 726-729, 729 (1997)	
2109	1997	Knowles, et. al., Current Opinions in Pediatrics, "Serious dermatologic reactions in children," 9:388-395, 391 (1997)	
2110	2000	Schulz, Sheridan, Ryan, et al., "A Ten Year Experience with Toxic Epidermal Necrolysis", J. Burn Care & Rehabilitation, pp. 199-204, 199-200 (May/June 2000)	
2111	2000	Garcia-Doval, et. al., Arch Dermatol, "Toxic Epidermal Necrolysis and Stevens Johnson Syndrome," Vol. 136, pp. 323-327, 324 (2000)	
2112	2001	Paquet, P, et al., "Treatment of Drug-induced toxic epidermal necrolysis (Lyell's syndrome) with intravenous human immunoglobulins," Burns, pp. 652-655 (2001)	
2113	2002	Foreman, et. al., Drug Safety, "Erythema Multiforme, Stevens-Johnson syndrome and Toxic Epidermal Necrolysis in Children," 25 (13) 965-972, 966 & 969 (2002)	
2114	2005	FDA-Legrenade, et al. Drug Safety, "Comparison of Reporting of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Association with Selective COX-2 Inhibitors", 28 (10); 917-924, 922 (2005)	
2115	2009	Mockenhaupt, et al., Academy, "Severe drug-induced skin reactions: clinical pattern, diagnostics and therapy" 7:142-162, 144 (2009)	

Exh No.	Date	Description	Defendants' Objections
2116	2009	Levi, et al., Pediatrics, "Medications at Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Children: A Pooled Analysis" 123 (2) e297-e304, e297 & e302 (2009)	
		Time to Onset of SJS and TEN in Published Literature	
2200	1978	Sternlieb P., et al., NY State Jour of Med, "Stevens-Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen", pp. 1239-43, (1978).	
2201	1984	Wintroub, B. U., et al., Current Perspectives in Immunodermatology, "Cutaneous Reactions to Drugs," pp.75-97, 85 (MacKie, R. M. (ed) Churchillill Livingstone 1984).	
2202	1989	Stern, R. S., et al., Pharmcol Skin, "Adverse Cutaneous reactions to Nonsteroidal Anti-Inflammatory Drugs," pp. 148-156, 150 (Hensby, C., et al. (eds.) Basel Karger 1989).	
2203	1989	Stern, R. S., et al., J Am Acad Dermatol, "Usefulness of Case report Literature in Determining Drugs Repsonsible for Toxic Epidermal Necrolysis," 21(2) 317-322, 320 (1989).	
2204	1989	Stern, R. S., et al., Primay Care, "Allergic Cutaneous Reactions to Drugs," 16(3) 713-727, 714 (1989).	
2205	1995	Sharma, V. K., et al., Ped Derm, "Clinical Pattern of Cutaneous Drug Eruption Among Children and Adolescents in North India," 12(2) 178-183, 180 (1995).	
2206	1996	Khoo, A. K. M., at al., Burns, "Toxic Epidermal Necrolysis in a Burns Centre: A 6-Year Review," 22(4) 275-278, 276 (1996).	
2207	1999	Fritsch, P.O., et al., Fitzpatrick's Dermatology in General Medicine, "Stevens-Johnson Syndrome - Toxic Epidermal Necrolysis," pp.644-654, 647 (5th ed., Freedberg, I.M., et al. (eds.) McGraw-Hill 1999).	
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Exh No.	Date	Description	Defendants' Objections
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2210	2003	Mockenahupt, M., et al., J Rheum, "The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Antiinflammatory Drugs: A Multinational Perspective," 30(10) 2234-2240, 2236 (Table 1) (2003).	
2211	2003	Britschgi, Markus, Pichler, Werner, et al., Current Drug Targets, Molecular Aspects of Drug Recognition by Specific T Cells", 4. 1-11, (2003).	
2212	2004	Taghian, M., et al., J Peds, "Acute Vanishing Bile Duct Syndrome After Ibuprofen Therapy in a Child," 273-276, 275 (Table) (Aug. 2004).	
2213	2005	Paquet, P., et al., J Oral Pathol Med, "Cystic Lesion of the Parotid Following Drug-Induced Toxic Epidermal Necrolysis" 34: 380-2 (2005).	
2214	2007	Yamane, Y., et al. Allergology Int'l, "Analysis of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Japan from 2000 to 2006," 56 (4) 1-7, 3 (2007).	
2215	2007	Rakasha, M. P., et al., Indian J Dermatol Venereol Leprol, "Clinical Study of Cutaneous Drug Eruption in 200 Patients," 74(80) 80-84, 81 (2007).	
2216	2007	Yawalkar, N., Drug Hypersensitivity, "Maculopapular Drug Eruptions," pp. 242-250, 246 (Pichler, W.J. (ed.) Basel, Karger 2007).	
2217	No date	Stern R., et al., Supplied by the British Library – "The World's Knowledge, Cutaneous Drug Reactions", Chapter 18, pp. 85-89. No date.	
		BRAIN INJURY / NEUROPATHY	
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Exh No.	Date	Description	Defendants' Objections
2301	1975	Mutina, E., et al., <u>Sov Med</u> , "Allergic Damage To The Nervous System In Stevens-Johnson Syndrome," July 15, 1975.	
2302	1979	Friedman, J., et al., <u>Neurology</u> , "Bilateral Facial Palsy Associated with Stevens-Johnson Syndrome," Vol. 29, pp. 1304-1306, (1979)	
2303	1985	De Rego, J., et al. <u>Hillside Journal of Clinical Psychiatry</u> , "Case Report Psychosis with Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis," Vol. 7 (2), pp. 141-148) (1985)	
2304	1989	Macove, M., <u>Necrol Psychiat</u> , "Particular Neurological Aspects in Vascular Autoimmune Diseases. I. Rheumatoid Purpura, Stevens-Johnson Syndrome, Rheumatoid Arthritis and Systemic Lupus Erythematosus," Vol. 27, pp. 241-248, (1989)	
2305	1989	McDonald, K., et al., <u>Jour of Burn Care & Rehab.</u> , "Rehabilitative Considerations for Patients with Severe Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis: A Case Report," Vol. 10(2), pp. 167-171, (1989)	
2306	1990	Moody, D., et al., <u>ANJR</u> , "Features of the Cerebral Vascular Pattern That Predict Vulnerability to Perfusion or Oxygenation Deficiency: An Anatomic Study," Vol. 11:431-439 (1990)	
2307	1990	Patterson, D., et al., <u>J. Burn Care Rehabil.</u> , "Post Traumatic Stress Disorder in Hospitalized Patients with Burn Injuries", Vol. 11, pp. 181-4 (1990).	
2308	1990	Patterson, d., et al., <u>J. Burn Care Rehabil.</u> , "Post Traumatic Stress Disorder in Hospitalized Patients with Burn Injuries", Vol. 11, pp. 181-4 (1990).	
2309	1993	Dagum, A., et al. <u>Jour of Burn Care & Rehab.</u> , "Severe Multiple Mononeuropathy in Patients with Major Thermal Burns," Vol. 14(4), pp. 440-445, (1993)	
2310	1993	Marquez, S., et al, <u>Brain</u> , "Neuropathy in Burn Patients," Vol, 116, pp. 471-483, (1993)	

Exh No.	Date	Description	Defendants' Objections
2311	1994	Powers, P., et al. <u>J. Burn Care Rehab.</u> , "Posttraumatic Stress Disorder in Patients with Burns", Vol. 15: 147-53 (1994).	
2312	1995	Latarjet, J., et al., <u>Burns</u> , "Pain in Burn Patients," Vol. 21(5), pp. 344-348, (1995)	
2313	1995	Margherita, A., et al., <u>Burn Neuropathy</u> , "Burn-Associated Peripheral Polyneuropathy," Vol. 74(1), pp. 28-32, (1995)	
2314	1995	Schulz, J., et al., <u>Burns</u> , "Pain in Burn Patients", Vol. 21:5, pp. 344-348 (1995)	
2315	1997	Khedr, E., et al., <u>Burns</u> , "Peripheral Neuropathy in Burn Patients," Vol. 23(718), pp. 579-583, (1997)	
2316	1997	Tanttula, K., et al., <u>Burns</u> , "Return to Employment After Burn," Vol. 23(4), pp. 341-344, (1997)	
2317	1997	Sandip, K., et al., <u>Burns</u> , "Adjunctive Methods of Pain Control in Burns", Vol. 23:5, pp. 404-412 (1997).	
2318	1998	Varney, N., et al., <u>Archives of Clinical Neuropsychology</u> , "Long-Term Neuropsychological Sequelae of Severe Burns," Vol. 13(8), pp. 737-749, (1998)	
2319	1998	Ulmer, J., <u>J. Burn Care Rehabil.</u> , "Burn Pain management: a Guideline-Based Approach", Vol 19:2, pp. 151-159 (1998).	
2320	1999	Yu, B., et al., <u>J Burn Care Rehabil.</u> , "Posttraumatic Stress Disorder in Patients with Burn Injuries," Vol. 20, pp. 426-433, (1999)	
2321	1999	Hopkins, R., et al., <u>Am J Respir Crit Care Med</u> , "Neuropsychological Sequelae and Impaired Health Status in Survivors of Severe Acute Respiratory Distress Syndrome," Vol. 160: 50-56 (1999)	
2322	1999	Fukunishi, I., <u>Psychother. Psychosom.</u> , "Relationship of Cosmetic Disfigurement to the Severity of Posttraumatic Stress Disorder in Burn Injury or Digital Amputation", Vol. 68, pp. 82-86 (1999).	

Exh No.	Date	Description	Defendants' Objections
2323	1999	Fleming, M., et al., <u>Journal of Traumatic Stress</u> , "Effects of Varying Scoring Rules of the Clinician Administered PTSD Scale (CAPS) for the Diagnosis of PTSD After Acute Burn Injury", Vol. 13:2, pp. 535-542 (1999).	
2324	2000	Sheridan, R., et al., <u>JAMA</u> , "Long-term Outcome of Children Surviving Massive Burns," Vol. 283(1), pp. 69-73, (2000)	
2325	2001	Druschky, A., <u>Intensive Care Med</u> , "Critical Illness Polyneuropathy: Clinical Findings and Cell Culture Assay of Neurotoxicity Assessed by a Prospective Study," Vol. 27, pp. 686-693, (2001)	
2326	2001	Kowalske, K., et al., <u>Jour of Burn Care & Rehab</u> , "Neuropathy After Bum Injury," Vol. 22(5), pp. 353-357, (2001)	
2327	2001	Jones, C., et al., <u>Crit Care Med</u> , "Memory, delusions, and the development of acute posttraumatic stress disorder-related symptoms after intensive care," Vol. 29, No. 3, pp.573-580 (2001).	
2328	2001	Madianos, M., et al., <u>Psychother. Psychosom</u> , "Psychiatric Disorders in Burn Patients: A Follow-Up Study", Vol. 70, pp, 30-37 (2001).	
2329	2001	Wiechman, S., et al., <u>J. Burn Care Rehabil</u> , "Rates, Trends, and Severity of Depression After Burn Injuries", Vol. 22, pp. 417-424 (2001).	
2330	2002	Auquier-Dunant, A., et al., <u>Arch Derm</u> , "Correlations Between Clinical Patterns and Causes of Erythema Multiforme Majus, Stevens-Johnson Syndrome, and Toxic Epidermal Necrolysis," Vol. 138:1019-1024 (2002)	
2331	2002	El Hamaoui, Y., et al., <u>Burns</u> , "Post-traumatic Stress Disorder in Burned Patients", Vol. 28, pp. 647-650 (2002).	
2332	2003	Van Loey, N., et al., <u>Am J Clin Dermatol</u> , "Psychopathology and Psychological Problems in Patients with Burn Scars: Epidemiology and Management," Vol. 4(4), pp. 245-272, (2003)	
2333	2003	Jones, C., et al., <u>Crit Care Med</u> , "Rehabilitation after critical illness: A randomized, controlled trial," Vol. 31, No. 10, pp. 2456-2461 (2003).	

Exh No.	Date	Description	Defendants' Objections
2334	2004	Jones, C., et al., <u>Intensive Care Med</u> , "Post-traumatic stress disorder-related symptoms in relatives of patients following intensive care," Vol. 30:456-460 (2004).	
2335	2004	Backonja, M., et al., <u>Pain Medicine</u> , "Pharmacologic Management Part 1: Better-Studied Neuropathic Pain Diseases," Vol. 5, No. S1, pp. S28-47 (2004).	
2336	2004	Weddell, R., <u>Nursing Times</u> , "Improving Pain management for Patients in a Hospital Burns Unit", Vol.100:11, p. 38 (2004).	
2337	2005	Haber, J., et al., <u>J Burn Care</u> , "Late Outcomes in Adult Survivors of Toxic Epidermal Necrolysis After Treatment in a Burn Center," Vol. 26, pp. 33-41, (2005)	
2338	2005	Weissenborn, K., et. al., <u>AIDS 2005</u> , "Neurological and neuropsychiatric syndromes associated with liver disease", 19 (suppl 3):S93-S98, (2005)	
2339	2005	"Neuropsychiatric Disorders on Ibuprofen", <u>Rev. Prescrire</u> , Vol. 25(261):350 (2005)	
2340	2006	Arora, M., et al., <u>Journal Compilation, The Royal Australian and New Zealand College of Psychiatrists</u> , "Stevens-Johnson Syndrome (SJS) Leading to Resolution of Mania," pp. 193-195, (2006)	
2341	2006	Hopkins, R., et, al., <u>American College of CHEST Physicians</u> , "Long-term Neurocognitive Function After Critical Illness", 130;869-878, (2006)	
2342	2006	Hopkins, R., et, al., <u>Curr Opin Crit Care</u> , "Assessing neurocognitive outcomes after critical illness: are delirium and long-term cognitive impairments related?", 12:388-394, (2006)	
2343	2006	Detry, O., et al., <u>World Gastroenterol</u> , "Brain Edema and Intracranial Hypertension in Fulminant Hepatic Failure: Pathophysiology and Management," Vol. 12(46): 7405-7512 (2006).	
2344	2006	Schneider, J., &Schulz, J., et al., <u>J. Burn Care Res</u> , "A Descriptive Review of Neuropathic-Like Pain After Burn Injury," Vol 27:524-528 (2006).	

Exh No.	Date	Description	Defendants' Objections
2345	2006	Schulz, J., et al., <u>J. Burn Care Res.</u> , "A Descriptive review of Neuropathic-Like Pain After Burn Injury", Vol. 524-528 (2006)	
2346	2007	Gorson, K., <u>The Neurologist</u> , "Vasculitic Neuropathies: An Update," Vol 13, pp. 12-19, (2007)	
2347	2007	Jackson, J., et al., <u>St. Thomas Foundation</u> , "Delirium as a Risk Factor for Long Term Cognitive Impairment in Mechanically Ventilated ICU Survivors," (2007)	
2348	2007	Schelling, G., <u>Progress in Brain Research</u> , "Post-traumatic stress disorder in somatic disease: lessons from critically ill patients," Vol. 167, pp. 229-237 (2007).	
2349	2007	Watts, G., et al., <u>Crit Care Resusc</u> , "Delirium in the intensive care unit: searching for causes and sources," Vol9:26-29 (2007).	
2350	2008	Elison, S., et al., <u>Intensive Care Med</u> , "Neuropsychological Function in Children Following Admission to Pediatric Intensive Care: A Pilot Investigation," Vol. 34:1289-1293 (2008).	
2351	2008	Herridge, M., et al., <u>Crit Care Clin</u> , "The Pathophysiology of Long-term Neuromuscular and Cognitive Outcomes Following Critical Illness," Vol. 24, pp. 179-199 (2008).	
2352	2008	Khan, J., et al., <u>Crit Care Clin</u> , "Mechanisms of Neuromuscular Dysfunction in Critical Illness," Vol. 24(1): 165-175 (2008)	
2353	2009	Baldwin, F., et al., <u>BMC Research Notes</u> , "Quality of Life and Persisting Symptoms in Intensive Care Unit Survivors: Implications for Care After Discharge," August 12, 2009.	
2354	2009	Bronner, M., et al., <u>Pediatr Crit Care Med</u> , "An Explorative Study on the Quality of Life and Psychological and Cognitive Function in Pediatric Survivors of Septic Shock," Vol.10, No. 6, pp. 636-642 (2009).	
2355	2009	Jackson, J., et al., <u>Southern Medical Assoc</u> , "Acute Respiratory Distress Syndrome, Sepsis, and Cognitive Decline: A Review and Case Study," Vol. 102, No. 11, pp. 1150-1157 (2009).	

Exh No.	Date	Description	Defendants' Objections
		DRUGS WITHDRAWN FROM THE MARKET BASED ON CASE REPORTS OR SERIES WITH NO CASE CONTROL STUDIES	
2400	1981	Ahmad, S., J. of the Royal Society of Med., "Ticrynafen-induced phenytoin toxicity: an interaction," 74:162-163 (1981).	
2401	1982	Manier, J., et al., Am. J. of Gastroent., ""Hepatotoxicity Associated with Ticrynafen—A Uricosuric Diuretic," Vol. 77(6): 401-404, (1982).	
2402	1983	Kiani, R., JAMA "Zomepirac-Induced Serum Sickness" 249(20): 2812-2813 (1983).	
2403	1984	Stern, R.S., JAMA "An Expanded Profile of Cutaneous Reactions to Nonsteroidal Anti-Inflammatory Drugs" 252(11):1433-1437 (1984).	
2404	1988	Henry, DA, Bailliere's Clinical Rheum., "Side-Effects of Non-Steroids Anti-Inflammatory Drugs" Vol. 2 No. 2, pp.425-454, 448 (1988).	
2405	1990	Martin, R., et al., Annals of Internal Medicine "The Clinical Spectrum of the Eosinophilia-Myalgia Syndrome Associated with L-Tryptophan Ingestion: Clinical Features in 20 Patients and Aspects of Pathophysiology" 113:124-134 (1990).	
2406	1994	Roujeau, J.C., et al. NEJM, "Severe Adverse Cutaneous Reactions to Drugs" 311:1272-1285 (1994).	
2407	1994	Blum, et. al., Clin. Inf. Dis. "Temafloracin Syndrome: Review of 95 Cases" 18:946-950 (1994).	
2408	1995	Roujeau, J.C., et al., NEJM, ""Medication Use And The Risk Of Stevens–Johnson Syndrome Or Toxic Epidermal Necrolysis"" 333:1600-1607 (1995).	
2409	2002	Shayne C. Gad, Drug Safety Evaluation (2002).	
2410	2003	Grillo, M., et al., Drug Metabolism and Disposition "Identification Of Zomepirac-S-Acyl-Glutathione In Vitro In Incubations With Rat Hepatocytes And In Vivo In Rat Bile," 31(11):1429-1436 (2003).	

Exh No.	Date	Description	Defendants' Objections
2411	2006	Goldkind, L., et al., Pharmacoepidemiology and Drug Safety, "A Systematic Review Of NSAIDs Withdrawn From The Market Due To Hepatotoxicity: Lessons Learned From The Bromfenac Experience," 15: 213–220 (2006).	
2412	2006	Goldkind, L., et al., Pharmacoepidemiology and Drug Safety, "A systematic review of NSAIDs withdrawn from the market due to hepatotoxicity: lessons learned from the bromfenac experience, " 15: 213–220 (2006).	
2413	2008	Geier, D., et al., Med. Sci. Monit. "RotaTeq vaccine adverse events and policy considerations"" 14(3):PH9-16. (2008).	
		Dear Doctor Letters / Letters to the Editor / FDA Press Releases	
2500	1997	Roche Laboratories 'Dear Doctor; Letter, December 1997.	Lacks authentication (Rule 901)
2501	1998	Wyeth-Ayerst Dear Healthcare Professional Letter. June 22, 1998.	Lacks authentication (Rule 901)
2502	1999	Glaxo Wellcome Dear Health Care Provider Letter November 1, 1999.	Lacks authentication (Rule 901)
2506	1999	July 1, 1999 Letter to Apotex Corp. - ANDA Ticlopidine approval and post approval Dear Doctor Letters.	Lacks authentication (Rule 901)
2507	1999	August 20, 1999 Letter to Eon Labs - ANDA Ticlopidine approval and post approval Dear Doctor Letters.	Lacks authentication (Rule 901)
2508	1999	August 20, 1999 Letter to Purepac Pharm. Co. - ANDA Ticlopidine approval and post approval Dear Doctor Letters.	Lacks authentication (Rule 901)
2509	1999	August 20, 1999 Letter to Teva - ANDA Ticlopidine approval and post approval Dear Doctor Letters.	Lacks authentication (Rule 901)
2510	1999	September 13, 1999 Letter to Par Pharm., Inc. - ANDA Ticlopidine approval and post approval Dear Doctor Letters.	Lacks authentication (Rule 901)
2511	2000	April 26, 2000 Letter to Danbury Pharmacal, Inc. - ANDA Ticlopidine approval and post approval Dear Doctor Letters.	Lacks authentication (Rule 901)
2503	2000	Janssen Pharmaceutica 'Dear Healthcare Provider' Letter April 2000.	Lacks authentication (Rule 901)
2512	2000	June 14, 2000 Syntex NDA Ticlopidine Approval adding Aplastic Anemia to Warning.	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
2504	2001	Bayer 'Dear Health Care Professional' Letter. May 21, 2001.	Lacks authentication (Rule 901)
2505	2001	Bayer 'Dear Health Care Professional' Letter. August 8, 2001.	Lacks authentication (Rule 901)
2513	2002	2002 Teva Dear Doctor Letter for Ticlopidine Hydrochloride	Lacks authentication (Rule 901)
2514	2002	October 17, 2002 Mutual NDA Bactrim approval & Dear Doctor Authority	Lacks authentication (Rule 901)
2515	2002	November 13, 2002 Pfizer Dear Healthcare Professional Letter for Bextra	Lacks authentication (Rule 901)
2516	2004	October 15, 2004 Pfizer Dear Healthcare Professional Letter for Bextra	Lacks authentication (Rule 901)
2517	2004	December 9, 2004 FDA "Questions and Answers: Strengthened Warnings on Bextra"	Lacks authentication (Rule 901)
2518	2005	April 7, 2005 FDA News "FDA Announces Series of Changes to the Class of Marketed Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)"	
2519	2007	November 2, 2007 King Pharmaceuticals Dear Prescriber Letter for Procanbid.	Lacks authentication (Rule 901)
2520	2008	Castandeda, C., at al., <u>Journal of Oncology</u> , Letter to Editor, "Erythema Multiforme/Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis in Lenalidomide-Treated Patients," (2008)	Lacks authentication (Rule 901)
2521	2008	2008 MPR Prescribing Alert Dear Healthcare Professional Letter.	Lacks authentication (Rule 901)
2522	2009	June 30, 2009 Teva Dear Healthcare Professional Letter for Beclazone.	Lacks authentication (Rule 901)
2523	2010	May 27, 2010 Teva Dear Healthcare Professional Letter for Warfarin.	Lacks authentication (Rule 901)
2524	2010	June 9, 2010 APP Dear Healthcare Professional Letter for Propofol.	Lacks authentication (Rule 901)
2525	2010	March 29, 2010 Mylan Canadian Dear Healthcare Professional Letter for Letrozole.	Lacks authentication (Rule 901)
2526	2010	April 6, 2010 Teva Canadian Dear Healthcare Professional Letter for Letrozole.	Lacks authentication (Rule 901)
2527	4/7/2005	FDA News, FDA Announces Series of Changes to the Class of Marketed NSAIDS	Lacks authentication (Rule 901)
		Underreporting	
2528	1993	Kessler, D., <u>JAMA</u> , "Introducing MEDWatch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems," Vol.269(21): pp. 2765-68 (1993).	

Exh No.	Date	Description	Defendants' Objections
2529	1996	MedWatch Continuing Education Article, "The Clinical Impact of Adverse Event Reporting," October 1996, p5 citing Scott, FDA reports less than 1% of serious ADRs reported	
2530	1999	Scott, H. D., et. al., "Physician reporting of adverse drug reactions. Results of the Rhode Island Adverse Drug Reaction Reporting Project", JAMA, Vol. 263, No. 13, (1990);Brewer, M.D., Timothy, et. al, "Postmarketing Surveillance and Adverse Drug Reactions", JAMA, Vol. 281, No.9, pages 281:824c829,(1999)	
2531	2004	Mittmann, Nicole, et. al, "Evaluation of the Extent of Under-Reporting of Serious Adverse Drug Reactions", Drug Safety, 27 (7),477 -487, (2004)	
2532	2005	FDA Alert for Healthcare Professionals for Isotretinoin (marketed as Accutane) 05/2005	
2533	2005	Excerpt from the Deposition of Marie Pinizzotto, In re: Hormaone Therapy Litigation. August 23, 2005.	Lacks authentication (Rule 901)
2534	2005	LeGranade, FDA p922 "given the likely 10-fold under-reporting of this event", Comparison of Reporting of SJS & TEN in Association with Selective COX-2 Inhibitors, FDA, Drug Safety 2005, 28(10)917-924	
2535	2006	"FDA Presentation OSE Analyses of Hepatic Adverse Events" Allen Brinker, M.D., December 2006	Lacks authentication (Rule 901)
		SENSITIZATION/RECHALLENGE	
2600	1972	Kauppinen K. Cutaneous Reactions to Drugs, A Clinical Study, Acta Dermato-Venereologica, 1972 Vol. 52, Supp. 68.	
2601	1993	Sharma V., et al., Pediatric Dermatology, "Clinical Pattern of Cutaneous Drug Eruption Among Children and Adolescents in North India," Vol. 12, No. 2, pp. 178-183, (1995).	
2602	1994	Roujeu, et al., The New Eng Jour of Med, "Severe Adverse Cutaneous Reactions to Drugs", Vol. 331, No. 19, pp. 1272-85, (Oct. 1994).	
2603	1996	Stern R. Shear N. Cutaneous Medicine & Surgery, 1996 Chapter 43, pp. 412-425, 414.	

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2608	2002	Chan E. Cronstein B. Molecular action of methotrexate in inflammatory diseases. Arthritis Research 2002, 4:4:266-273	
2609	2007	Pichler, W.J., <u>Drug Hypersensitivity</u> . Basel, Switzerland: Karger, 2007.	
2610	2007	De Rojas MV, Dart JK, Saw VP. The natural history of Stevens Johnson syndrome: patterns of chronic ocular disease and the role of systemic immunosuppressive therapy. Br J Ophthalmol. Aug 2007; 91(8): 1048-53.	
2611	2008	Ferrell PB. Carbamazepine, HLA-B*1502 and risk of Stevens-Johnson syndrome and toxic epidermal necrolysis: US FDA recommendations. Pharmacogenomics 2008. 9(10):1543-1546.	
2612	2008	FDA Drug Safety Newsletter, V.1, Issue 2, Winter 2008, TUMOR NECROSIS FACTOR ALPHA (TNF- α) ANTAGONISTS, Reports of serious skin reactions associated with use of infliximab (marketed as REMICADE), etanercept (marketed as ENBREL), and adalimumab (marketed as HUMIRA).	

Exh No.	Date	Description	Defendants' Objections
2613	2009	Tseng SCG. Acute management of Stevens-Johnson syndrome and toxic epidermal necrolysis to minimize ocular sequelae. Editorial. Am J Ophthalmol 147[6]:949-51; 2009.	
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2703	1991	2701Chan, et al. & Foster, JAMA, "Ocular Cicatricial Pemphigoid Occurring as a Sequela of Stevens-Johnson Syndrome", Vol. 266, No. 11; 1543-46 (1991).	
2704	1996	Power WJ, Saidman SL, Zhang DS, et al. HLA typing in patients with ocular manifestation of Stevens- Johnson syndrome. Ophthalmology 1996;103:1406-1409.	
2705	2005	Di Pascuale MA, Espana EM, Liu D T-S, Kawakita T, Li W, Gao YY, Baradaran-Rafii A, Raju VK, Tseng SCG. Correlation of corneal complications with eyelid cicatricial pathologies in Tiffanys with Steven Johnson syndrome and toxic epidermal necrolysis syndrome. Ophthalmology 112:904-912, 2005	
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2802	1993	Bastuji-Garin S, Rzany B, Stern RS, Shear NH, Naldi L, Roujeau Je. Clinical classification of cases of toxic epidermal necrolysis, Stevens-Johnson syndrome, and erythema multiforme. Arch Dermatol.1993;129:92-96.	
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2804	1995	Assier H, Bastuji-Garin S, Revuz J, et al. Erythema multiforme with mucous membrane involvement and Stevens-Johnson syndrome are clinically different disorders with distinct causes. Arch Dermatol.1995;131:539-543.	

Exh No.	Date	Description	Defendants' Objections
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Exh No.	Date	Description	Defendants' Objections
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3003	1995	Roujeau J., et al., New England Jour of Med, "Medication Use and the Risk of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis," Vol. 333, No. 24, pp. 1600-7 (1995)	
3004	1996	McIvor RA, Zaidi J, Peters WJ, et al. Acute and chronic respiratory complications of toxic epidermal necrolysis. J Burn Care Rehabil. 1996;17:237-240.	
3005	1998	Sheridan, NEJM, "Objective Estimates of the Probability of Death From Burn Injuries", Vol. 338 No. 6, pp. 362-368 (1998)	
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3007	2000	Schulz, Sheridan, Ryan, et al., "A Ten Year Experience with Toxic Epidermal Necrolysis", J. Burn Care & Rehabilitation, pp. 199-204, 199-200 (May/June 2000)	
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3102	1992	Patterson R, Grammer L, Greenberger PA, et al. Stevens Johnson syndrome (SJS): effectiveness of corticosteroids in management and recurrent SJS. Allergy Proc. 1992; 13:89-95.	
3103	1992	Saia P, Caumes E, Chosidow O., et al. Drug-induced toxic epidermal necrolysis (Lyell syndrome) in patients infected with the human immunodeficiency virus. J. Am Acad Dermatol. 1992;26:567-574.	
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3206	1984	Wintroub, B. U., et al., Cutaneous Reactions to Drugs. Current Perspectives in Immunodermatology 1984 75-97 (MacKie, R. M. (ed) Churchillill Livingstone).	
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3209	1988	Delattre JY. Safai B. Posner JB. Erythema multiforme and Stevens-Johnson Syndrome in patients receiving cranial irradiation and phenytoin. Neurology 1988. 38:194-8	
3210	1990	Roujeau JC, Chosidow O., Saiag P, et al. Toxic epidermal necrolysis (Lyell syndrome). Am Acad Dermatol. 1990;23:1039-1058.	
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3215	1996	Rzany B, Hering O., Mockenhaupt M, et al. Histopathological and epidemiological characteristics of patients with erythema exudativum multi forme major, Stevens-Johnson syndrome and toxic epidermal necrolysis. Br J Dermatol. 1996; 135:6-11.	
3216	1996	Power WJ, Saidman SL, Zhang DS, et al. HLA typing in patients with ocular manifestation of Stevens- Johnson syndrome. Ophthalmology 1996;103:1406-1409.	
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3224	2002	Nassif A. Bensussan A. Dorothee G. Mami-Chouaib F. Bachot N. Bagot M. Boumsell L. Roujeau JC. Drug specific cytotoxic T-cells in the skin lesions of a patient with toxic epidermal necrolysis. J Invest Dermatol 2002. 118:728-33	
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3234	2008	Cartotto R. Mayich M. Nickerson D. Gomez M. SCORTEN accurately predicts mortality among toxic epidermal necrolysis patients treated in a burn center. J Burn Care Res 2008 Jan-Feb. 29(1):141-6	
3235	2008	Chung WH. Hung SI. Yang JY. Su SC, Huang SP. Wei CY. Chin SW. Chiou CC. Chu SC. Ho HC. Yang CH. Lu CF. Wu JY. Liao YD. Chen YT. Granulysin is a key mediator for disseminated keratinocyte death in Stevens-Johnson syndrome and toxic epidermal necrolysis Nat Med 2008 Dec.14(12):1343-50. Epub 2008 Nov 23	
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3238	2008	Mayes T. Gottschlich M. Khoury J. Warner P. Kagan R. Energy requirements of pediatric patients with Stevens-Johnson syndrome and toxic epidermal necrolysis. Nutr Clin Pract 2008 Oct-Nov. 23(5):547-50	
3239	2008	Mockenhaupt M. Viboud C. Dunant A. Naldi L. Halevy S. Bouwes Bavinck JN. Sidoroff A. Schneck J. Roujeau JC. Flahault A. Stevens-Johnson syndrome and toxic epidermal necrolysis: assessment of medication risks with emphasis on recently marketed drugs. The EuroSCARstudy. J Invest Dermatol 2008 Jan. 128(1):35-44	

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3603	1994	Roujeau J., et al., The New Eng Jour of Med, "Severe Adverse Cutaneous Reactions to Drugs", Vol. 331, No. 19, pp. 1272-85, (Oct. 1994).	

Exh No.	Date	Description	Defendants' Objections
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3605	1995	Cote, B., et al, Arch Dermatol., "Clinicopathologic Correlation in Erythema Multiforme and Stevens-Johnson Syndrome" Vol. 131, pp. 1268-1272 (1995).	
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3607	1997	Weston, William L. et al., Arch Dermatol. "Herpes Simplex Virus Associated Erythema Multiforme in Prepubertal Children", Volume 151 (10) pp. 1014-1016, (1997).	
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Exh No.	Date	Description	Defendants' Objections
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3614	2009	Levi N., et al., "Medications as Risk Factors of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Children: A Pooled Analysis", <i>Pediatrics: Official Journal of the American Academy of Pediatrics</i> . 123.2 (2009): e297-e304.	
Government Regulations/Guidance/Memos			
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3701	1982	U.S. Department of Health and Human Services Press Release. August 5, 1982.	
3702	1986	Health and Human Services News. May 1, 1986.	
3703	1986	FDA Talk Paper. "Suprofen Update" July 24, 1986.	
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3705	1989	"Withdrawal of Rotavirus Vaccine Recommendation" Center for Disease Control, MMWR 38(46):785-788 (November 24, 1989).	
3706	1989	Center for Disease Control, MMWR 38(46):785-788 (November 24, 1989).	
3707	1992	57 Federal Register 61437, FDA Guideline for Postmarketing Reporting of Adverse Tab 20 Drug Experiences, Docket No. 85D-0249, December 24, 1992	
3708	1992	US General Accounting Office ("GAO") Report to the Chairman, Subcommittee on Regulation, Business Opportunities, and Energy, Committee on Small Business, House of Representatives, GAO/PEMD-92-9, "Nonprescription Drugs, Over the Counter and Underemphasized." Date: January 10, 1992.	

Exh No.	Date	Description	Defendants' Objections
3709	1992	GAO Testimony Before the Subcommittee on Regulation, Business Opportunities and Energy Committee on Small Business House of Representatives, GAO/T-PEMD-92-8, "Over the Counter Drugs, Gaps and Potential Vulnerabilities in the Regulatory System." Date: April 28, 1992.	
3710	1996	Medwatch Continuing Education Article, "The Clinical Impact of Adverse Event Reporting" October 1996.	
3711	1996	Correspondence from Dr. Wiley Chambers (FDA) to Vivian Chester (McNeil) re. labeling requirements. Attachment: NSAID Package Insert Labeling Template. Date: December 20, 1996 <i>Bates# LFR01273267 to LFR01273268. (Also McNeil 101)</i>	
3712	1997	"Warning Labeling Changes for New Heart Drug Posicor" FDA Talk Paper, December 19, 1997.	
3713	1997	FDA Guidance For Industry; Postmarketing Adverse Experience Reporting for Human Dmg and Licensed Biologic Products: Clarification of What to Report, August 1997	
3714	1998	Federal Register, Rules and Regulations Vol. 63, No. 230. 21 CFR part 201 et al., "Prescription Drug Labeling: Medication Guide Requirements: Final Rule," Publication Date Decembr 1, 1998.	
3715	1998	"Roche laboratories Announces Withdrawal of Posicar From the Market" FDA Talk Paper June 8, 1998.	
3716	1998	FDA Talk Paper. "Wyeth-Ayerst laboratories Announces the Withdrawal of Duract from the Market" June 22, 1998.	
3717	1999	FED REG: Federal Register, Rules and Regulations Vol. 64, No. 54 – "Over-The-Counter Human Drugs; Labeling Requirements." Publication date: March 17, 1999.	
3718	1999	Federal Register, Part II Department of Health and Human Services 21 CFR, Part 201, et al., March 17, 1999	
3719	2000	Health and Human Services News. March 21, 2000.	

Exh No.	Date	Description	Defendants' Objections
3720	2000	Lexis Publishing's Code of Federal Regulations. Title 21, Food and Drugs. Chapter 1, FDA and Department of Health and Human Services. Subchapter D, Drugs for Human Use. Part 314, Applications for FDA Approval to Market a New Drug. Subpart B- Applications.	
3721	2000	Guidance for Industry: Content and Format of the Adverse Reactions Section of the Labeling for Human Drugs and Biologics, CDER, May 2000,	
3722	2001	FDA Guidance For Industry: Postmarketing Safety Reporting for Human Dmg and Biological Products Including Vaccines, March 2001	
3723	2001	FDA News (website article) – "OTC Labeling: Questions and Answers." (January 3, 2001)	
3724	2002	Guidance for FDA Staff and Industry Compliance Policy Guides Manual Sec. 460.200. (2002)	
3725	2002	Guidance for FDA Staff and Industry Compliance Policy Guides Manual Sec. 460.200. (2002)	
3726	2002	FDA News (website article) – "The New Over-the-Counter Medicine Label: Take a Look." (June 24, 2002).	
3727	2002	FED REG: Federal Register, Proposed Rules Vol. 67, No. 162 – "Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph, and Related Labeling." Date: August 21, 2002.	
3728	2003	Federal Register Vol 68, No. 7, p.1469. (2003)	
3729	2003	Title 21- Food and Drugs Chapter 1-Food and Dmg Administration, Department of Health and Human Services, SubChapter D - Drugs for Human Use, Part 314.80, pages 121-127, (2003)	
3730	2004	Food and Drug Administration. "FDA issues public health advisory on Vioxx as its manufacturer voluntarily withdraws the product". www.fda.gov/bbs/topics/news/2004/NEW01122.html .	

Exh No.	Date	Description	Defendants' Objections
3731	2004	Food and Drug Administration. "FDA talk paper: Bextra label updated with boxed warning concerning severe skin reactions and warning regarding cardiovascular risk". www.fda.gov/bbs/topics/ANSWERS/2004/ANS01331.html.	
3732	2004	FED REG: Excerpt from Federal Register, §314.70 – 21 CFR Ch. I, pp. 111-112. Date: April 1, 2004 Edition.	
3733	2004	FED REG: CFR-Code of Federal Regulations, Title 21--Food and Drugs/ Subchapter D--Drugs for Human Use/ Part 314--Applications for FDA Approval to Market a New Drug/ Subpart B--- Applications. Cite: 21 CFR 314.70. (Current through April 7, 2004 issue of the Federal Register.	Lacks authentication (Rule 901)
3734	2004	FED REG: Federal Register, Rules and Regulations, §314.70 [revised], Vol. 69, No. 68 – "Supplements and other changes to an approved application." Date: April 8, 2004.	
3735	2004	FED REG: CFR-Code of Federal Regulations, Labeling Requirements for Prescription Drugs and/or Insulin §201.56 and §201.57. (Current through the May 20, 2004 issue of the Federal Register).	
3736	2005	FDA Memorandum of 4/6/05 re NSAIDs, withdrawal of Bextra.	
3737	2005	FDA Alert April 7, 2005.	
3738	2005	Food and Drug Administration. "Alert for healthcare professionals: celecoxib (marketed as Celebrex)".www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.pdf.	
3739	2005	Food and Drug Administration, Information for Patients and Providers, www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM103420	
3740	2005	FDA Food & Drug Administration - -FDA News - - "FDA Announces Series of Changes to the Class of Marketed Non-Steroidal Anti-inflammatory Drugs (NSAIDs) dated April 7, 2005	

Exh No.	Date	Description	Defendants' Objections
3741	2005	Department of Health & Human Services, Memorandum, dated February 27, 2006, RE: Consult #819, received December 23, 2005 from HFD-130 and assigned 011 December 27, 2005 - This consult is for a review of the dermatologic aspects of the sponsor's response and provide comments to DPP	
3742	2005	Letter from Roger Salisbury, M.D., Professor of Surgery, Chief of Plastic Surgery, to Food and Drug Administration Re: Citizen Petition to Request Risk Assessment of the Risks from SJS and TEN associated with Ibuprofen ... (February 15, 2005).	
3743	2005	FED REG: 21 CFR § 314.94 – Code of Federal Regulations, “Content and format of an abbreviated application.” Current through April 1, 2005. (Tackett depo, 4/16/09, Ex. 11-2, Robinson v. McNeil)	
3744	2005	FDA News (website articles) – (2005) <ul style="list-style-type: none"> • “FDA Announces Series of Changes to the Class of Marketed Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)” • “Questions and Answers – FDA Regulatory Actions for the COX-2 Selective and NON-Selective Non-Steroidal Anti-inflammatory drugs (NSAIDs)” • “FDA Public Health Advisory – FDA Announces Important Changes and Additional Warnings for COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).” 	Lacks authentication (Rule 901)
3745	2005	Letter with attachments from Bob Rappaport (FDA-Center for Drug Evaluation and Research) re. labeling request (2005).	Lacks authentication (Rule 901)
3746.1	2005	Letter with attachments from Charles Ganley (FDA-Office of Non-Rx Drugs Center for Drug Evaluation and Research) re. Supplemental Labeling Request (2005).	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
3746.2	2005	Letter with attachments from Curtis Rosebraugh (FDA-Div. of Non-Rx Clinical Eval., Office of Non-Rx Products, Center for Drug Evaluation and Research) re. Supplemental Labeling Request (2005).	Lacks authentication (Rule 901)
3747	2005	Memorandum from Dr. John K. Jenkins (Director, Office of New Drugs-OND) to NDA files 20-998, 21-156, 21-341, 214-042. Subject: Analysis and recommendations for Agency action regarding non-steroidal anti-inflammatory drugs and cardiovascular risk. Date: April 6, 2005. Bates# DEX006112-DEX006130.	Lacks authentication (Rule 901)
3748	2005	FDA NSAID Supplementary Request Letter with Labeling Template and Medication Guide dated June 15, 2005.	
3749	2005	FDA's response letter to Dr. Roger Salisbury re. Citizen's Petition. Date: August 5, 2005.	
3750	2006	Federal Register Vol. 61 No. 98.	
3751	2006	FED REG: Federal Register, Rules and Regulations, 21 CFR Parts 201, 314, and 601, Vol. 71, No. 15 – "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products." Date: January 24, 2006. Bates# DEX006001-DEX006077.	
3752	2006	FDA Response letter to Dr. Roger Salisbury re. Citizen's Petition. Date: June 22, 2006.	
3753	2007	Federal Register Vol 72 No. 114 p. 32852-3. (2007)	
3754	2007	FDA "Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)," Date created: June 15, 2005, updated April 19, 2007.	
3755	2007	Public Law 110-85, Title IX-Enhanced Authorities Regarding Postmarket Safety of Drugs, Subtitle A – Postmarked Studies and Surveillance, Sec. 901. Date: September 27, 2007.	
3756	2008	FED REG: Excerpt from Federal Register, §201.57 – 21 CFR Ch I, pp. 24-25. Date: April 1, 2008 Edition. Bates# DEX005980-DEX005995.	

Exh No.	Date	Description	Defendants' Objections
3757	2008	FED REG: Excerpt from Federal Register, §314.70 – 21 CFR Ch. I, pp. 111-112. Date: April 1, 2008 Edition. <i>Bates# DEX005996-DEX005997.</i>	
3758	2008	FED REG: CFR-Code of Federal Regulations, Title 21--Food and Drugs/ Chapter I—Food and Drug Administration, Department of Health and Human Services, Subchapter D--Drugs for Human Use/ Part 314--Applications for FDA Approval to Market a New Drug/ Subpart B---Applications. [Title 21, Volume 5] [Revised as of April 1, 2008] Cite 21 CFR 314.70.	
3759	2008	FED REG: 21 CFR § 314.98 – Code of Federal Regulations, “Postmarketing reports.” Current through October 23, 2008. (Tackett depo, 4/16/09, Ex. 11-3, Robinson v. McNeil)	
3760	2009	2009 WL 529172 (U.S.), <i>Wyeth, Petitioner v. Diana Levine</i> , No. 06-1249, in the United States Supreme Court. Argued November 3, 2008. Decided March 4, 2009.	
3761	No Date	FDA Question and Answers on Regulatory Actions for the COX-2 Selective and Non--Selective Non-Steroidal Anti-inflammatory drugs (NSAIDs)	
3762	No Date	Department of Health & Human Services NDA Labeling Revision Request	Lacks authentication (Rule 901)
3763	No Date	Title 21 - Food and Drugs, Chapter 1 - - Food and Drug Administration Department of Health and Human Services, SubChapter D – Drugs for Human Use, Part 314	
3764	No Date	Ibuprofen Industry Association materials	Lacks authentication (Rule 901)
3765	No Date	EMA Revision to NSAID labeling	Lacks authentication (Rule 901)
3766	No Date	FDA Memorandum on NSAID labeling	Lacks authentication (Rule 901)
3767	No Date	FDA Provigil Memorandum and related documents by Sponsor, by FDA and FDA Psychopharmacology Committee;	Lacks authentication (Rule 901)
		Labeling	
3800	2000	PDR 2000, Physician's Desk Reference, Zithromax, Pfizer Inc. /2389 Bextra, November 2004, LAB-0266-4.0	

Exh No.	Date	Description	Defendants' Objections
3801	2000	Package Insert Adult Motrin Rx 1982 -- 2000	
3802	2004	Foreign Labeling, Dolormin for Children	Lacks authentication (Rule 901)
3803	1982-2000	Package Insert Adult Motrin OTC	
3804	2002	Ibuprofen (Adult) 1978 - - 1989 Ibuprofen (Adult) 1990 - -1996 Ibuprofen (Adult) 1997 - 2002 NAIDS / Ibuprofen Pediatrics	Lacks authentication (Rule 901)
		Vaginal Damage from SJS & TEN	
3900	1981	Graham-Brown, R., et al., British J Obstet & Gyn, "Vaginal Stenosis Due to Bullous Erythema Multiforme (Stevens-Johnson Syndrome): Case Report", Vol. 88, pp. 1156-1157 (1981)	
3901	1985	Marquette, et al., Obstetrics & Gynecology, "Introital Adenosis Associated with Stevens-Johnson Syndrome," Vol. 66, No.1, pp. 143-45, (1985)	
3902	1988	Wilson, E., et al., Obstet. & Gyn., "Vulvovaginal Sequelae of Stevens-Johnson Syndrome and Their Management", Vol. 71:2, pp. 478-480 (1988).	
3903	1990	Bonafe, J., et al., Clin. & Exp. Dermatol., "Introital Adenosis Associated with the Stevens-Johnson Syndrome", Vol. 15, pp. 356-357 (1990).	
3904	1997	Meneux E., et al., Jour of Reproductive Med, "Vulvovaginal Sequelae in Toxic Epidermal Necrolysis," Vol. 42, No.3, pp. 153-6, (1997)	
3905	1998	Roujeau J., et al., Obstetrics & Gynecology, "Vulvovaginal Involvement in Toxic Epidermal Necrolysis: A Retrospective Study of 40 Cases," Vol. 91, No.2, pp. 283-7, (1998)	
3906	2002	Hart, R., et al., Pediatr. Adolesc. Gynecol., "Vaginal Adhesions Caused by Stevens-Johnson Syndrome" Vol. 15, pp. 151-152 (2002).	
3907	2005	Noel J-C., et al., British Jour of Dermatology, "Vulval Adenosis Associated with Toxic Epidermal Necrolysis," Vol. 153 No.2, pp. 440-466 (2005)	
3908	2006	Emberger, M., et. al., Editor, European Academy of Dermatology and Venereology, "Vaginal adenosis induced by Stevens-Johnson syndrome", 20, 868-902, (2006)	

Exh No.	Date	Description	Defendants' Objections
3909	1988	Kratzert K., et al., Obstetrics & Gynecology, "Pregnancy Post-Stevens- Johnson Syndrome: Case Report and Review of the Literature," Vol. 72, No.3, Part 2, pp. 447-51, (1988)	
3910	2007	Fischer, G., J. Reproductive Med., "Vulvar Fixed Drug Eruption: A Report of 13 Cases", Vol. 52:2, pp. 81-86 (2007).	
3911	2007	Neuman, M., et al., Translational Research, "Apoptosis in Ibuprofen-Induced Stevens-Johnson Syndrome", Vol. 149, pp. 254-259 (2007).	
Limitations & Failures of the FDA			
4000	1982	GAO – Report To The Secretary of Health and Human Services – FDA Can Further Improve Its Adverse Drug Reaction Reporting System, (1982)	Lacks authentication (Rule 901)
4001	1982	GAO -- Report To The Secretary of Hcaith and Human Services - FDA Can Further Improve Its Adverse Drug Reaction Reporting System, (1982)	Lacks authentication (Rule 901)
4002	1992	Statement of Kwai-Cheung Chan, GAO/T=PEDMID-92-5, (1992)	Lacks authentication (Rule 901)
4003	1992	GAO Testimony Before the Subcommittee on Regulation, Business Opportunities and Energy Committee on Small Business House of Representatives, GAO/T-PEMD-92-8, “Over the Counter Drugs, Gaps and Potential Vulnerabilities in the Regulatory System.” Date: April 28, 1992.	Lacks authentication (Rule 901)
4004	1992	GAO - Report to the Chairman, Subcommittee on Regulation. Business Opportunities and Energy, Committee on Small Business House of Representatives -- Non□Prescription Drugs - Over the Counter and Underemphasized, GAO/PEMD -92-9, (1992)	Lacks authentication (Rule 901)
4005	1992	GAO - Testimony Before the Subcommittee on Regulations, Business Opportunities and Energy Committee on Small Business House of Representatives, Over the Counter Drugs, Gaps and Potential Vulnerabilities in the Regulatory System, GAO/T-PEMID-92-5, (1992)	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
4006	1992	GAO -Testimony Before the Subcommittee on Human Resources and Inter-government Relations Committee on Government Operations House of Representatives - Nonprescription Drugs -- Over the Counter and Underemphasized Statement of Kwai-Cheung Chan, GAO/T=PEDM1D-92 -5, (1992)	Lacks authentication (Rule 901)
4007	2000	GAO - Testimony - Adverse Drug Events - Substantial Problem but Magnitude Uncertain, Statement of Janet Heinrich, Associate Director, Health Financing and Public Health Issues, Health and Human Services Division, GAO/T-HEHS--00-53, pp 1-12, (2000)	Lacks authentication (Rule 901)
4008	2003	Department of Health and Human Services, Office Of, Inspector General-- FDA's Review Process for New Drug Applications -- A Management Review (2003)	Lacks authentication (Rule 901)
4009	2007	FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology, (2007)	Lacks authentication (Rule 901)
4010	2007	GAO Testimony Before the Subcommittee and Health, Committee on Energy and Commerce, House of Representatives, -- Drug Safety Further Actions Needed to Improve FDA's Postmarket Decision - Making Process, (2007)	Lacks authentication (Rule 901)
4011	2007	FDA Science and Mission at Risk - Synopsis of A Report of the Food and Drug Administration's Science Board (2007)	Lacks authentication (Rule 901)
4012	2008	Testimony of Dr. Garret A. Fitzgerald before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce House of Representatives on Science and Mission at Risk: FDA's Self Assessment. Date: January 29, 2008.	Lacks authentication (Rule 901)
4013	2008	Testimony, Gregory Curfman (Editor NEJM) before House Committee on Oversight and Investigations, Preemption – Drugs and Medical Devices. Date: May 14, 2008.	Lacks authentication (Rule 901)
4014	2008	Testimony of Catherine E. Woteki, Ph.D., R.D. Science and Mission at Risk: FDA's Self Assessment Subcommittee on Oversight and Investigations Committee on Energy and Commerce, (2008)	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
4015	2008	Testimony of Gail H. Cassell, PhD, before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce House of Representatives on Science and Mission at Risk: FDA's Self Assessment, (2008)	Lacks authentication (Rule 901)
4016	2008	Testimony Former Commissioner United States Food and Drug Administration Before The House Committee on Oversight and Government Reform, Hearing On: Should FDA Drug and Medical Device Regulation Bar State Liability Claims?, (2008)	Lacks authentication (Rule 901)
4017	2008	Testimony House Committee on Oversight and Investigations Preemption -- Drug and Medical Devices (2008)	Lacks authentication (Rule 901)
4018	2009	GAO - Report to the Congress - High Risk Series An Update (2009)	Lacks authentication (Rule 901)
4019	2009	U.S. Supreme Court- Wyeth, Petitioner vs Diana Levine No, 06-1249 (2009)	
4020	2009	Department of Health and Human Services, Food and Drug Administration Office of Device Evaluation, Letter to President Barack H. Obama, Exhibit A1, pp 1- 6, April 2, (2009)	Lacks authentication (Rule 901)
4021	2009	Certified Letters to President Barrack Obama of 4.2.09 and John Podesta of 1.7.09.	Lacks authentication (Rule 901)
4022	No Date	Statement of Dale Nordenberg, M.D. before the U.S. Congress Committee on Energy and Commerce, Subcommittee on Oversight and Investigations,	Lacks authentication (Rule 901)
		DRUG SAFETY/SURVEILLANCE	
4100	1990	Scott, H. D., et. al., "Physician reporting of adverse drug reactions. Results of the Rhode Island Adverse Drug Reaction Reporting Project", JAMA, Vol. 263, No. 13, (1990);	
4101	1996	Mitchell, Allen A., et. al., "When a Randomised Controlled Trial is Needed to Assess Drug Safety", Drug Safety, 13(1): 125-24, (1996)	
4102	1998	Moore, Thomas J., et. al, "Time to Act on Drug Safety", JAMA, Vol. 279, No. 19, pages 1571-1573, (1998)	
4103	1998	Lazarous, Jason, et. al, "Incidence of Adverse Drug Reactions in Hospitalized Patients", JAMA, Vol. 279 No. 15, pages 1200-1205, (1998)	

Exh No.	Date	Description	Defendants' Objections
4104	1999	Waller, P. Pharmacoepidemiology and Drug Safety, "Responding to Drug Safety Issues", 8: 535-552, (1999)	
4105	1999	Brewer, M.D., Timothy, et. al, "Postmarketing Surveillance and Adverse Drug Reactions", JAMA, Vol. 281, No.9, pages 281:824c829,(1999)	
4106	2001	Ioannidis, John P. M.D., et. al, "Completeness of Safety Reporting in Randomized Trials", JAMA, Vol. 285, No.4, pages 437 - 443, (2001)	
4107	2002	Lasser, M.D. Karen E., et. al, "Timing of New Black Box Warnings and Withdrawals for Prescription Medications", JAMA, Vol. 287, No. 17, pages 2215 - 2220, (2002)	
4108	2002	Omar, M A, et.al, "FDA adverse event reports on statin-associated rhabdomyolysis", The Annals of Pharmacotherapy, Vol. 36, No.2, pages 288-295, (2002)	
4109	2004	Psaty, M.D., Bruce M., et. al., "Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions", JAMA, Vol. 292, No. 21, pages 2622 - - 2646, (2004);	
4110	2004	Strom, M.D. Brian L., "Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions", JAMA, Vol. 292, No, 21, pages 2643 - - 2646, (2004)	
4111	2004	Mittmann, Nicole, et. al, "Evaluation of the Extent of Under-Reporting of Serious Adverse Drug Reactions", Drug Safety, 27 (7),477 -487, (2004)	
4112	2005	Bennett, M.D., Charles. L., et. al, "The Research on Adverse Drug Events and Reports (RADAR) Project", JAMA, Vol. 293, No. 17, pages 2131-2140; Letters 1206 - 1107, (2005)	
4113	2006	Furberg, Curt D." et. al, "The FDA and Drug Safety: A Proposal for Sweeping Changes", Archives of Internal Medicine, Alliance for Human Research Protection (2006).	
		Dexibuprofen	
4200	1989	Pang Y., et al., <u>Australian Prescriber</u> , "Stereoisomerism in Drug Molecules," Vol. 12, No. 1, pp. 19-25, (1989)	

Exh No.	Date	Description	Defendants' Objections
4201	1989	Pang Y., et al., Australian Prescriber, "Stereoisomerism in Drug Molecules," Vol. 12, No. 1, pp. 19-25, (1989)	
4202	1990	Geisslinger, G., et al., <u>Eur J Clin Pharmacol</u> , "Pharmacokinetics of S(+)- and R(-)-ibuprofen in volunteers and first clinical experience of S(+)-ibuprofen in rheumatoid arthritis," Vol. 38:493-497 (1990).	
4203	1991	Ertel W., et al., <u>Jour of Trauma</u> , "Eicosanoids Regulate Tumor Necrosis Factor Synthesis After Hemorrhage in Vitro and In Vivo," pp. 609-16, (1991)	
4204	1991	Between Inhibition of Thromboxane Production and the Plasma Unbound Concentration of S(+)-Ibuprofen," Vol. 31, pp. 131-8, (1991)	
4205	1991	"Elicosanoids Regulate Tumor Necrosis Factor Synthesis After Hemorrhage In Vitro and In Vivo" by Wolfgang Ertel, M.D., et al. <u>The Journal of Trauma</u> , Vol. 31 No. 5 (1991)	
4206	1991	Evans A., et al., <u>J Clin Pharmac</u> , "Effect of Racemic Ibuprofen Dose on the Magnitutde and Duration Latelet Cycle-Oxygenase Inhibition: Relationship Between Innhibition of Thromboxane Production and the Plasma Unbound Concentration of S(+)-Ibuprofen, Vol. 31, No. 31, pp. 131-138, (1991)	
4207	1994	Paquet Pl., et al., <u>Arch Dermatol</u> , "Macrophages and Tumor Necrosis Factor a in Toxic Epidermal Necrolysis," Vol. 130, pp. 605-16, (1994)	
4208	1995	Chlud K., <u>J Clin Pharmacol</u> , "Evaluation of Tolerance and Efficacy of S(+)-Ibuprofen (Seractil) in Daily Practice: A Post-Marketing Surveillance Study in 1400 Patients," Vol. 35, pp. 921-40, (1995)	
4209	1996	Rahlfs V., et al., <u>J Clin Pharmacol</u> , "Reevaluation of Some Double-Blind, Randomized Studies of Dexibuprofen (Seractil): A State-of-the-Art Overview," Vol. 36, pp. 33S-40S, (1996)	
4210	1996	Paul C., (Wolkenstein & Roujeau) et al., <u>Brit Jour of Dermatol</u> , "Apoptosis as a Mechanism of Keratinocyte Death in Toxic Epideanal Necrolysis," Vol. 134, pp. 710-14, (1996)	

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4211	1996	Klausner J., et al., <u>Clin Immunology & Immunopathology</u> , "Short Analytical Review: Thalidomide as an Anti-TNF- α Inhibitor: Implications for Clinical Use," Vol. 81, No. 3, pp. 219-23, (1996)	
4212	1996	Evans, A., <u>Clin Pharmacol</u> , "Pharmacodynamics and Pharmacokinetics of the Profens: Enantioselectivity, Clinical Implications, and Special Reference to S(+)-Ibuprofen," Vol. 36, ppp. 7S-15S, (1996)	
4213	1996	Rahlf V., et al., <u>J Clin Pharmacol</u> , "Reevaluation of Some Double-Blind, Randomized Studies of Dexibuprofen (Seractil): A State-of-the-Art Overview," Vol. 36, pp. 33S-40S, (1996)	
4214	1996	Klausner J., et al., <u>Clin Immunology & Immunopathology</u> , "Short Analytical Review: Thalidomide as an Anti-TNF- α Inhibitor: Implications for Clinical Use," Vol. 81, No. 3, pp. 219-23, (1996)	
4215	1996	"Pharmacodynamics and Pharmacokinetics of the Profens: Enantioselectivity, Clinical Implications, and Special Reference to S(+)-Ibuprofen," by Allan M. Evans. <u>Clin Pharmacol</u> 36:7S-15S (1996)	
4216	1997	OTC Business News, "Reform Boost to Austrian Market?" pp. 1-2, (1997)	Lacks authentication (Rule 901)
4217	1997	Pharma Marketletter, "Spirig Gains First Approval for S-Optifen," pp. 1, (1997)	Lacks authentication (Rule 901)
4218	1997	Walker P., et al., <u>Jour of Immunology</u> , "Role of Fas Ligand (CD95L) in Immune Escape the Tumor Cell Strikes Back," Vol. 158, pp. 4521-24, (1997)	
4219	1997	Paquet P., et al., <u>Amer Jour of Dermatol</u> , "Erythema Multiforme and Toxic Epidermal Necrolysis: A Comparative Study," Vol. 19, No. 2, pp. 127-32, (1997)	
4220	1997	Salomon D., et al., <u>Annales De Dermatol</u> , "Five Cases of Toxic Epidermal Necrolysis Treated by Intravenous Immunoglobulins with Favorable Results," Suppl 124, pp. S216-17, (1997)	
4221	1997	OTC Business News, "Reform Boost to Austrian Market?" pp. 1-2, (1997)	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
4222	1997	Pharma Marketletter, "Spirig Gains First Approval for S-Optifen," pp. 1, (1997)	Lacks authentication (Rule 901)
4223	1997	Walker p., et al., <i>Jour of Immunology</i> , "Role of Fas Ligand (CD95L) in Immune Escape the Tumor Cell Strikes Bck," Vol. 158, pp. 4521-24, (1997)	
4224	1997	Paquet P., et al., <u>The Alder Journal of Dermatopathology</u> , "Erythema Multiforme and Toxic Epidermal Necrolysis: A Comparative Study", Vol. 19, No.2, pp. 127-32, (1997).	
4225	1997	Salomon D., et al., <u>Annales De Dermatologie et de Venereologie</u> . "Five Cases of Toxic Epidermal Necrolysis Treated by Intravenous Immunoglobulins with Favorable Results," pp. S216-7, (1997).	
4226	1998	Viard I., et al., <u>Science</u> , "Inhibition of Toxic Epidermal Necrolysis by Blockade of CD95 with Human Intravenous Immunoglobulin," Vol. 282, pp. 490-3, (1998)	
4227	1998	Wolkenstein P., et al., <u>Lancet</u> , "Randomized Comparison of Thalidomide Versus Placebo in Toxic Epidermal Necrolysis," Vol. 352, pp. 1586-89, (1998)	
4228	1998	Viard, I., et al., <u>SCIENCE</u> , "Inhibition of TOXIC Epidermal Necrolysis by Blockade of CD95 with Human Intravenous Immunoglobulin", Vol 282, pp. 490-193, (1998)	
4229	1998	Wolkenstein P., et al., <u>Lancet</u> , "Randomized Comparison of Thalidomide Versus Placebo in Toxic Epidermal Necrolysis," Vol. 352, pp. 1586-89, (1998)	
4230	1999	Fritsch P., et al., <u>Fitzpatrick's Dermatol in Gen Med</u> , "Stevens-Johnson Syndrome-Toxic Epidermal Necrolysis," Chap. 59, pp. 644-54, (1999)	
4231	1999	Luster M., et al., <u>Critical Reviews in Toxicology</u> , "Tumor Necrosis Factor a and Toxicology," Vol. 29, No. 5, pp. 491-511, (1999)	
4232	1999	Arnold R., et al., <u>Jour of Immunology</u> , "Crosstalk Between Keratinocytes and T Lymphocytes Via Fas/Fas Ligand Interaction: Modulation by Cytokines," pp. 7140-7, (1999)	

Exh No.	Date	Description	Defendants' Objections
4233	1999	Fritsch P., et al., <u>Dermatology in General Medicine</u> , "Stevens-Johnson Syndrome: Toxic Epidermal Necorlysis", Vol. 1, 5th Edition, pp. 644-54, (1999).	
4234	1999	Luster M., et al., <u>Critical Reviews in Toxicology</u> , "Tumor Necrosis Factor & Toxicology", Vol. 29, No. 5, pp. 491-511, (1999)	
4235	1999	Arnold R., et al., <u>Jour of Immunology</u> , "Crosstalk Between Keratinocytes and T Lymphocytes Via Fas.Fas Ligand Interaction: Modulation by Cytokines," pp. 7140-7, (1999)	
4236	2000	Singer F., et al., <u>Inter Jour of Clin Pharma & Therapeutics</u> , "Evaluation of the Efficacy and Dose-Response Relationship of Dexibuprofen (S(+)-Ibuprofen) in Patients with Osteoarthritis of the Hip and Comparison with Racemic Ibuprofen Using the WOMAC Osteoarthritis Index," Vol. 38, No. 1, pp. 15-24, (2000)	
4237	2000	Trent DIS, "DI Dispatch: A Current Awareness Newsletter," pp. 1-7, (2000)	
4238	2000	Bon A., et al., <u>Clin Rheumatol</u> , "Treatment of Non-Malignant Pain in the Dutch GP Population: An Analysis of Treatment Standards, Prescription Habits and Basic Attitudes," Suppl 1, pp. S2-5, (2000)	
4239	2000	Mascagni P., et al., <u>Eur Cytokine Netw</u> , "R- and S-Isomers of Nonsteroidal Anti-Inflammatory Drugs Differentially Regulate Cytokine Production," "Vol. 11, No. 2, pp. 185-92, (2000)	
4240	2000	Singer F., et al., <u>Inter Jour of Clin Pharma & Therapeutics</u> , "Evaluation of the Efficacy and Dose-Response Relationship of Dexibuprofen (S(+)-Ibuprofen) in Patients with Osteoarthritis of the Hip and Comparison with Racemic Ibuprofen Using the WOMAC Osteoarthritis Index," Vol. 38, No. 1, pp. 15-24 (2000)	
4241	2000	Trent DIS, "DI Dispatch: A Current Awareness Newsletter," pp. 1-7, (2000)	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
4242	2000	Bon A., et al., <u>Clin Rheumatol</u> , "Treatment of Non-Malignant Pain in the Dutch GP Population: An analysis of Treatment Standards, Prescription Habits and Basic Attitudes," Suppl 1, pp. S2-5, (2000)	
4243	2000	Mascagni, P., et al., <u>Cytokine News</u> , "R- and S-isomers of nonsteroidal anti-inflammatory drugs differentially regulate cytokine production", Vol. 11, No. 2, pp. 185-192, (2000)	
4244	2001	Paquet P., et al., <u>Burns</u> , "Treatment of Drug-Induced Toxic Epidermal Necrolysis (Lyell's Syndrome) With Intravenous Human Immunoglobulin," Vol. 27, pp. 652-5, (2001)	
4245	2001	Zuurmond W., <u>Clin Rheumatol</u> , "Pain Treatment With NSAIDs, Primary Focus on Ibuprofen," Suppl 1, pp. S6-S8, (2001)	
4246	2001	Phleps W., <u>Clin Rheumatol</u> , "Overview on Clinical Data of Dexibuprofen," Suppl 1, pp. S15-S21, (2001)	
4247	2001	Evans A., <u>Clin Rheumatol</u> , "Comparative Pharmacology of S(=)-Ibuprofen and (RS)-Ibuprofen," Suppl 1, pp. S9-14, (2001)	
4248	2001	Evans A., <u>Clin Rheumatol</u> , "Comparative Pharmacology of S(+)-Ibuprofen and (RS)-Ibuprofen," Suppl. 1: S9-S14 (2001)	
4249	2001	Paquet, P., et al., <u>BURNS</u> 27, "Treatment of drug-induced toxic epidermal Necrolysis (Lyell's syndrome) with intravenous human immunoglobulin's", pp. 652-655, (2001)	
4250	2001	Zuurmond W., <u>Clin Rheumatol</u> , "Pain Treatment with NSAIDs, Primary Focus on Ibuprofen," Suppl 1, pp. S6-S8, (2001)	
4251	2001	Phelps W., <u>Clin Rheumatol</u> , "Overview on Clinical Data of Dexibuprofen," Suppl 1, pp. S15-S21, (2001)	
4252	2001	"Comparative Pharmacology of S(+)-Ibuprofen and (RS)-Ibuprofen," by A.M. Evans. <u>Clin Rheumatol</u> (Suppl 1): S0-S14 (2001)	
4253	2002	Correia O., et al., <u>J Am Acad Dermatol</u> , "Increased Interleukin 10, Tumor Necrosis Factor α , and Interleukin 6 Levels in Blister Fluid of Toxic Epidermal Necrolysis," Vol. 47, No. 1, pp. 58-62, (2002)	

Exh No.	Date	Description	Defendants' Objections
4254	2002	Posadas S., et al., <u>Blood Cells, Molecules & Diseases</u> , "Gene Expression Levels of Cytokine Profile and Cytotoxic Markers in Non-Immediate Reactions to Drugs," Vol. 29, No. 2, pp. 179-89, (2002)	
4255	2002	New Medicines Authorized in Spain in 2002	Lacks authentication (Rule 901)
4256	2002	Correia O., et al., <u>J Am Acad Dermatol</u> , "Increased Interleukin 10, Tumor Necrosis Factor α , and Interleukin 6 Levels in Blister Fluid of Toxic Epidermal Necrolysis," Vol. 47, No. 1, pp. 58-62, (2002)	
4257	2002	Posadas S., et al., <u>Blood Cells, Molecules, and Diseases</u> , "Gene Expression Levels of Cytokine Profile and Cytotoxic Markers in Non-Immediate Reactions to Drugs", Vol. 29, No. 2, pp. 179-89, (2002)	
4258	2002	New Medicines Authorized in Spain in 2002.	Lacks authentication (Rule 901)
4259	2003	Kaehler S., et al., <u>Inflammopharmacology</u> , "Dexibuprofen: Pharmacology, Therapeutic Uses and Safety," Vol. 11, No. 4-6, pp. 371-83, (2003)	
4260	2003	White P., <u>Anesth Analg</u> , "Can the Use of Specific Isomers Improve the Safety and Efficacy of Nonsteroidal Antiinflammatory Drugs?" Vol. 97, pp. 309-10, (2003)	
4261	2003	Hutt, A., et al., <u>Acta Facultatis Pharmaceuticae Universitatis Comenianae</u> , "The Chiral Switch: The Development of Single Enantiomer Drugs From Racemates," pp. 7-23, (2003)	
4262	2003	Bonabello A., et al., <u>Anesth Analg</u> , "Dexibuprofen (S(+)-Isomer Ibuprofen) Reduces Gastric Damage and Improves Analgesic and Antiinflammatory Effects in Rodents," Vol. 97, pp. 402-8, (2003)	
4263	2003	Hawel R., et al., <u>Inter lour of Clin Pharma & Therapeutics</u> , "Comparison of the Efficacy and Tolerability of Dexibuprofen and Celecoxib in the Treatment of Osteoarthritis of the Hip," Vol. 41, No. 4, pp. 153-64, (2003)	

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4264	2003	Kaehler S., et al., <u>Inflammapharmacology</u> , "Dexibuprofen: Pharmacology, Therapeutic Uses and Safety," Vol. 11, No. 4-6, pp. 371-83, (2003)	
4265	2003	White P., <u>Anesth Analg</u> , "Can the Use of Specific Isomers Improve the Safety and Efficacy of Nonsteroidal Antiinflammatory Drugs?" Vol. 97, pp. 309-10, (2003)	
4266	2003	Hutt, A., et al., <u>Acta Facultatis Pharmaceuticae Universitatis Comenianae</u> , "The Chiral Switch: The Development of Single Enantiomer Drugs From Racemates,	
4267	2003	Bonabello A., et al., <u>Anesth Analg</u> , "Dexibuprofen (S(+)-Isomer Ibuprofen) Reduces Gastric Damage and Improves Analgesic and Antiinflammatory Effects in Rodents," Vol. 97, pp. 402-8, (2003)	
4268	2004	Nassif A.(Roujeau) et al., <u>J Invest Dermatol</u> , "Evaluation of the Potential Role of Cytokines in Toxic Epidermal Necrolysis," Vol. 123, pp. 850-5, (2004)	
4269	2004	Valentova J., et al., <u>Ceska Slav Farm</u> , "Chiral Switch: Pure Enantiomers of Drugs Instead of Racemic Mixtures," Vol. 53, No. 6, pp, 285-93, (2004)	
4270	2004	Germany Pharmaceutical Market, "Industry News Publications: Dexibuprofen," (2004)	Lacks authentication (Rule 901)
4271	2004	Gupta A., et al., <u>Jour of Cutan Med & Surg</u> , "A Review of the Use of Infliximab to Manage Cutaneous Dermatoses," pp. 77-89, (2004)	
4272	2004	Balogh Z., et al., <u>National Rheumatology and Physiotherapy Institute, General Pediatric Rhemathology</u> , "New Treatment Possibilities in Pediatric Rheumatology," Vol. 4, No. 4, pp. 1-4, (2004)	
4273	2004	Somogyi, A., et al., <u>Australian Prescriber</u> , "Inside the isomers: the tale of chiral switches," Vol. 27, No. 2, pp. 47 - 49 (2004).	

Exh No.	Date	Description	Defendants' Objections
4274	2004	Garcia-Martin, E., et al., <u>Clinical Pharmacology and Therapeutics</u> , "Interindividual variability in ibuprofen pharmacokinetics is related to interaction of cytochrome P450 2C8 and 2C9 amino acid polymorphisms," Vol. 76(2): 119-127 (2004).	
4275	2004	Hawel R., et al., <u>Inter Jour of Clin Pharma & Therapeutics</u> , "Comparison of the Efficacy and Tolerability of Dexibuprofen and Celecoxib in the Treatment of Osteoarthritis of the Hip," Vol. 41, No. 4, pp. 153-64, (2003)	
4276	2004	Nassif A., et al., <u>J Invest Dermatol</u> , "Evaluation of the Potential Role of Cytokines in Toxic Epidermal Necrolysis," Vol. 123, pp. 850-5, (2004)	
4277	2004	Valentova J., et al., <u>Ceska Slav Farm</u> , "Chiral Switch: Pure Enantiomers of Drugs Instead of Racemic Mixtures," Vol. 53, No. 6, pp. 285-93, (2004)	
4278	2004	<u>Germany Pharmaceutical Market</u> , "Industry News Publications: Dexibuprofen," (2004)	Lacks authentication (Rule 901)
4279	2004	Gupta A., et al., <u>Jour of Cutan Med & Surg</u> , "A Review of the use of Infliximab to Manage Cutaneous Dermatoses," pp. 77-89, (2004)	
4280	2008	Balogh, Z., et al., <u>National Rheumatology and Physiotherapy Institute, General Pediatric Rheumatology</u> , "New Treatment Possibilities in Pediatric Rheumatology, Vol. 4, No 4, pp. 1-4, (2004)	
4281	2009	Yoon, Jonh Seo, et al., <u>British Journal of Clinical Pharmacology</u> , "The effects and safety of dexibuprofen compared with ibuprofen in febrile children caused by upper respiratory tract infections", 66:6, 854-860, (2008)	
4282	2009	Kollenz, C., et al., <u>Gynecol Obstet Invest</u> , "ADIDAC Trial: Analgesia with Dexibuprofen versus Ibuprofen in Patients suffering from Primary Dysmenorrhea: A Crossover Trail", 67:25-31, (2009)	

Exh No.	Date	Description	Defendants' Objections
4283	2010	Kumaresan, C., et al., <u>International J of Current Pharmaceutical Research</u> , "S+ Ibuprofen (Dexibuprofen): The Superior Non Steroidal Anti-Inflammatory Agents For Development Of Pharmaceuticals," Vol. 2, No. 3, pp. 1-3 (2010).	
4284	No date	Evans A., et al., <u>J Clin Pharmacol</u> , "Effect of Racemic Ibuprofen Dose on the Magnitude and Duration Platelet Cyclo-Oxygenase Inhibition: Relationship	
4285	No date	U.S. and European Patents Relating to Dexibuprofen	Lacks authentication (Rule 901)
		PILS	
4300	No date	Prilosec OTC Patient Information Leaflet	Lacks authentication (Rule 901)
4301	No date	Degree Clinical Protection Patient Information Leaflet	Lacks authentication (Rule 901)
4302	No date	Ibuprofen Tablets, USP Patient Information Leaflet	
4303	No date	Package Inserts for Seractil. No date.	Lacks authentication (Rule 901)
4304	No date	Chapstick Patient Information Leaflet	Lacks authentication (Rule 901)
4305	No date	Ibuprofen Patient Information Leaflet - Johnson & Johnson - England	Lacks authentication (Rule 901)
		McNEIL DOCS	
4400	1974	NDA 17-463 Side Effects and Dose Level for Motrin Protocol 012 173, 8/8/74	Lacks authentication (Rule 901)
4401	1976	NDA 17-463, Motrin Tablets, (ibu) BI - annual report, September 10, 1976, LFR00107593, Vol. 1.1	
4402	1976	Motrin Tablets, NDA 17-463, (ibu) Bi-Annual Report, September 10, 1976, Vol. II	
4403	1976	NDA 17-463, Motrin Tablets (ibu) Bi-Annual Report, March 2, 1976 Vol. IV .	
4404	1981	Motrin Tablets, NDA 17-463, (ibu) Progress Report, Vol. 6 – Adverse Reactions, September 30, 1981, LFR00125727	
4405	1983	McNeil Memorandum Subject: Arthritis Advisory Committee Meeting Handouts, dated September 14, 1983	

Exh No.	Date	Description	Defendants' Objections
4406	1983	Ibuprofen Review prepared for: David E. Collins by Marsha M. Silberstein, M.D., Barbara H. Korberly, Pharm D. dated August 12, 1983	
4407	1984	McNeil Memorandum RE: IBUPROFEN NDA PROJECT, dated January 11, 1984, MC064778	
4408	1984	McNeil PETITION FOR RECONSIDERATION NDA 19-012 & NDA 18-989 dated June 18, 1984.	
4409	1984	McNeil PETITION FOR RECONSIDERATION NDA 19-012 & NDA 19-989 dated June 18, 1984 MC067238 & FDC Reports 46(13): T&C-I (March 26) 1984, Trade & Govt. Memos OTC Ibuprofen Labeling based on Rx Package insert information	Lacks authentication (Rule 901)
4410	1984	McNeil Memorandum to Robert Temple, M.D., RE: Ibuprofen- Summary Basis of Approval, dated May 31, 1984	
4411	1984	Bellevue Hospital Center Letter to Anthony R. Temple, best updating on ibuprofen from Lewis Goldfrank, dated September 12, 1984	
4412	1985	NDA 19-012, Nuprin Tablets Adverse Reactions, ADR's from Clinical Trials in Elderly Patients, January 29, 1985, Vol. 27	
4413	1985	McNeil Memorandum Subject: National Kidney Foundation dated May 23, 1985	Lacks authentication (Rule 901)
4414	1988	Mc Neil Letter to FDA regarding New Drug Application Ibuprofen Pediatric Suspension 80mg 15ml, dated March 31, 1988	Lacks authentication (Rule 901)
4415	1989	Graph of SRS 1980 Through 1989 17 years or younger, Motrin, Advil, Rufen, Ibuprofen Nuprin	Lacks authentication (Rule 901)
4416	1990	McNeil Letter Subject: Minutes of Industry Meeting with FDA Post Marketing Surveillance Program - Ibuprofen suspension, dated January 29, 1990 .	
4417	1991	<i>Index of FDA 1639s</i> Being Submitted for the Time Period 07/01/1991 Through 07/20/1992, Motrin Tablets NDA 17-463	Lacks authentication (Rule 901)
4418	1993	BUFS - Draft Final Report, dated November 2, 1993	Lacks authentication (Rule 901)
4419	1993	Medical Officer Review, NDA 20-516 (Supplement to NDA 19-842), dated December 22, 1993, pages 1 -29.	

Exh No.	Date	Description	Defendants' Objections
4420	1994	Department of Health, Education and Welfare, Public Health Service NDA 17-463, September 19, 1994, To: Schumann, PhD, From: J. Richard Crout, MD	Lacks authentication (Rule 901)
4421	1997	McNeil's spontaneous reports for NDA 17-463 & 19-012 (Rx. and OTC Motrin IB); and, McNeil's/PNU's spontaneous reports for other single ingredient ibuprofen products between 1973-1997	Lacks authentication (Rule 901)
4422	2005	Correspondence between FDA and Wyeth regarding adding a warning about SJS to OTC label, and Wyeth's filing of serious skin reactions in May of 2005;	Lacks authentication (Rule 901)
4423	2005	Package Insert Children's Motrin Rx, PDR 1994 - 2005	
4424	2009	McNeil - Briefing Materials for Drug Safety and Risk Management Anesthetic and Life Support and Non-Prescription Drugs Advisory Committee Meeting June 29-30, 2009.	Lacks authentication (Rule 901)
4425	2009	Materials submitted by McNeil at Joint Advisory Committee Meetings (DSaRM and NDAC)-June 2009, Docket No. FDA-2009-N-0138-012)	Lacks authentication (Rule 901)
4426	No date	NDA 19-842 Pedia-Profen Ibuprofen Suspension Request for FDA Meeting dated 6/11/92, Regulatory Copy	
4427	No date	BUFS Total cases hospitalized with cutaneous and mucocutaneous	Lacks authentication (Rule 901)
4428	No date	Boston Fever Study	Lacks authentication (Rule 901)
4429	No date	BUFS Final Study Report Advisory Meeting Minutes	Lacks authentication (Rule 901)
4430	No date	Frequency of SJS Docket Number 2005P-0072/CP1 page 3	Lacks authentication (Rule 901)
4431	No date	Presentation to the Arthritis and Non-Prescription Drugs Advisory Committees on the switch of Children's Motrin Ibuprofen Suspension from Prescription to nonprescription status, pages 1 – 269.	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
4432	No date	Presentation to the Arthritis and Non-Prescription Drugs Advisory Committees on the switch of Children's Motrin Ibuprofen Suspension from Prescription to nonprescription status, pages 270	Lacks authentication (Rule 901)
4433	No date	FD-356H New Drug Application for Coated Compressed Tablets 'Motrin(ibuprofen, U-18,53), Vol 1.1, Part 1 & 2	
4434	No date	Motrin 17-463, Three Month Update, LFR00101478, Vol. I	
4435	No date	NDA 17-463, Three Month Update, LFR00101939, Vol. II	
4436	No date	NDA 17-463, Motrin Update, LFR00102924, Vol. IV	
4437	No date	Motrin Osteoarthritis Study- Table 41 Protocol 320, LFR00103190	
4438	No date	C 14-171, Upjohn, Initial Clinical Report - Rheumatoid Arthritis	Lacks authentication (Rule 901)
4439	No date	C27-136, Adverse Reactions and concomitant Therapy, LFR 00025190	Lacks authentication (Rule 901)
4440	No date	C15-64, Upjohn, Initial Clinical Report - Rheumatoid Arthritis LFR 00019750	Lacks authentication (Rule 901)
4441	No date	Motrin (ibuprofen, U-18,573), NDA 17-463, First Quarterly Update Drug Experience Reports, FD-1639	Lacks authentication (Rule 901)
4442	No date	Department of Health, Education, and Welfare, Public Health Service, To: Dr. Schumann, From J. Richard Crout, M.D. LFR00149316	Lacks authentication (Rule 901)
4443	No date	Motrin, NDA 17-463, LFR00121007, Reaction, Erythema Multiform	
4444	No date	Motrin Tablets, NDA 17-463, Reaction Stevens Johnson Syndrome LFR00126730	Lacks authentication (Rule 901)
4445	No date	McNeil's Failure to File/Report Scientific Literature in NDAs and Postmarketing reports for Motrin Products;	Lacks authentication (Rule 901)
4446	No date	Failure to Report SJS cases to Final BUFS Study Report, FDA Medical Officer, and U.S. Non-Prescription Drug Advisory Committee (NDAC)	Lacks authentication (Rule 901)
4447	No date	Petition for Reconsideration by McNeil Risk of Death higher for Ibuprofen	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
4448	No date	Ibuprofen Pediatric Suspension, 80mg / 5ml New Drug Application, Overview of Sponsored Studies, NDA 19-842, MCO6A 000878	Lacks authentication (Rule 901)
4449	No date	NDA 19-842 Summary Basis of Approval	
4450	No date	Ibuprofen Pediatric Suspension, 80mg / 5ml New Drug Application, Other Studies and Information, MC06A 000908	
4451	No date	McNeil Safety Policies and Procedures for Adverse Event Collection and Reporting ADEs; CRS data entry and retrieval; Safety Information Exchange between McNeil/J&J and Pharmacia & Upjohn (PNU);	Lacks authentication (Rule 901)
4452	No date	Foreign reporting between PNU and McNeil; and other McNeil and J&J safety policies	Lacks authentication (Rule 901)
4453	No date	Spontaneous Reports of Serious Skin and liver reactions	Lacks authentication (Rule 901)
4454	No date	Source documents; emails between McNeil PV and upper management.	Lacks authentication (Rule 901)
4455	No date	Tentative Final Monograph (McNeil's NDAs, Wyeth's NDAs, Federal Register for 200 mg Ibuprofen, and related materials;	
4456	No date	Pre-NDA and Pre-Approval meeting notes/correspondence for Pediaprofen and Rx. to OTC Switch for Children's Motrin	Lacks authentication (Rule 901)
4457	No date	McNeil/J&J Safety policies and procedures for adverse experience reporting;	Lacks authentication (Rule 901)
4458	No date	Annual and Periodic Reports for NDAs 19-842, 20-516, 17-463, 19-899, 19-012, 20-601, 20-602, 20-603, 21-128;	Lacks authentication (Rule 901)
4459	No date	McNeil's Response to Docket No. 1977N-0094L, FDA-Proposed Rule IAAA; and see Briefing	Lacks authentication (Rule 901)
4460	No date	McNeil Product Safety Reviews-PSURs	Lacks authentication (Rule 901)
4461	No date	Foreign labeling for ibuprofen products	Lacks authentication (Rule 901)
4462	No date	Adverse event data concerning acetaminophen products;	Lacks authentication (Rule 901)
4463	No date	Materials from Anthony Temple, M.D.'s files, including; the Goldfrank and Koberly reports	Lacks authentication (Rule 901)
4464	No date	DDMAC letters to McNeil regarding Children's Motrin	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
4465	No date	NDA 17-463 Clinical trial data, case reports and ADEs;	Lacks authentication (Rule 901)
4466	No date	Supplemental Applications and clinical trial data and ADEs;	Lacks authentication (Rule 901)
4467	No date	Quarterly Updates and Bi-Annual reports to NDA 17-463;	Lacks authentication (Rule 901)
4468	No date	Postmarketing Adverse Experiences from NDA 17-463;	Lacks authentication (Rule 901)
4469	No date	Progress reports for Clinical trial data for NDA 17-463;	Lacks authentication (Rule 901)
4470	No date	Annual and Periodic ADE reports for 17-463;	Lacks authentication (Rule 901)
4471	No date	NDA 19-012 Clinical trial data, case reports and ADEs;	Lacks authentication (Rule 901)
4472	No date	Supplemental Applications and clinical trial data and ADEs; Motrin Migraine	Lacks authentication (Rule 901)
4473	No date	Quarterly Updates and Bi-Annual reports to NDA 19-012;	Lacks authentication (Rule 901)
4474	No date	Postmarketing Adverse Experiences from NDA 19-012;	Lacks authentication (Rule 901)
4475	No date	Progress reports for Clinical trial data for NDA 19-012;	Lacks authentication (Rule 901)
4476	No date	Annual and Periodic ADE reports for 19-012;	Lacks authentication (Rule 901)
4477	No date	FDA Correspondence, SNDAs and CBE changes for Motrin IB, Nuprin or Haltran products;	Lacks authentication (Rule 901)
4478	No date	Submissions in Response to FDA requests to add SJS/TEN warnings to FDA;	Lacks authentication (Rule 901)
		Expert Reports	
4500	12/6/2010	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Laura Bix, Ph. D.	
4501	12/6/2010	Curriculum Vitae of Laura Bix, Ph.D.	
4502	1922	Stevens A, Johnson F. A new eruptive fever associated with stomatitis and ophthalmia: Report of two cases in children. <i>American Journal of Diseases of Children</i> . 1922;24:526-533.	
4503	1956	Lyell A. Toxic epidermal necrolysis: An eruption resembling scalding of the skin. <i>British Journal of Dermatology</i> . 1956;68(11):355-361.	

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4504	1978	Sternlieb. Steven-Johnson Syndrome plus Toxic Hepatitis due to ibuprofen. <i>New York State Journal of Medicine</i> . 1978;1239-1243.	
4505	1984	Stern R, Bigby M. An expanded profile of cutaneous reactions to nonsteroidal anti-inflammatory drugs: Reports to a specialty-based system for spontaneous reporting of adverse reactions to drugs. <i>JAMA</i> . 1984;252(11):1433-1437.	
4506	1984	Weisman R, Howland M, Goldfrank L. Ibuprofen: An analysis of safety and efficacy. August 1984.	
4507	1984	Associated Press. Safety of painkiller ibuprofen argued by experts. <i>Spokane Chronicle</i> 1984 June 14;10.	
4508	1987	Goldstein S, Wintroub B, Elias P, Wuepper K. Toxic epidermal necrolysis: unmuttiding the waters. <i>Archives of Dermatology</i> . 1987;123:1153-1156.	
4509	1988	Lehto M, Miller J. The Effectiveness of Warning Labels. <i>Journal of Products Liability</i> . 1988;11:225-270.	
4510	1990	Lumpkin J, Strutton D, Lim C, Lowrey S. A shopping orientation based prescription for the treatment of OTC medication misuse among the elderly. <i>Health Marketing Quarterly</i> . 1990;8(1/2):95-110.	
4511	1991	DeJoy D. A Revised Model of the Warnings Process Derived from Value-Expectancy Theory. Human Factors Society 22nd Annual Meeting. Santa Monica, CA Human Factors Society; 1991: 1043-1047.	
4512	1993	Bastuji-Garin S, Rzany B, Stern R, Shear N, Naldi L, Roujeau J. Clinical classification of cases of toxic epidermal necrolysis, Stevens-Johnson Syndrome and Erythema Multiforme. <i>Archives of Dermatology</i> . 1993;129:92-96.	
4513	1994	Roujeau J, Stern R. Severe Adverse Cutaneous Reactions to Drugs. <i>The New England Journal of Medicine</i> . 1994;331(19):1272-1285.	

Exh No.	Date	Description	Defendants' Objections
4514	1995	Roujeau J, Kelly J, Naldi L, et al. Medication use and the risk of Stevens-Johnson syndrome or toxic epidermal necrolysis. <i>The New England Journal of Medicine</i> . 1995;333(24):1600-1607.	
4515	1996	Henrich W, Agodoa L, Barrett B, et al. National Kidney Foundation Position Paper: Analgesics and the kidney: Summary and recommendations to the Scientific Advisory Board of the National Kidney Foundation from an Ad Hoc Committee of the National Kidney Foundation. <i>American Journal of Kidney Diseases</i> . 1996;27(1):162-165.	
4516	1996	Wogalter M, Laughery K. Warning! Sign and Label Effectiveness. <i>Current Directions in Psychological Science</i> . 1996;5:33-37.	
4517	1996	Wogalter M, Margurno A, Scott K, Dietrich D. Facilitating information acquisition for Over-the-Counter drugs using supplemental labels. The Human Factors and Ergonomics Society's 40th Annual Meeting; 1996.	
4518	1996	Sansgiry S, Cady P. Can picture use effectively enhance the understanding of nonprescription drug labels in older adults? <i>Journal of Geriatric Drug Therapy</i> . 1996;10(4):51-69.	
4519	1997	Huskisson EC. Seminars in arthritis and rheumatism. <i>Antiinflammatory Drugs</i> . 1977;VII(1):1-20.	
4520	1998	Srivastava M, Perez-Atayde A, Jonas M. Drug-associated acute-onset vanishing bile duct and Stevens-Johnson syndromes in a child. <i>Gastroenterology</i> . 1998;115:743-746.	
4521	1998	Rousseau G, Lamson N, Rogers W. Designing Warnings to Compensate for Age-Related Changes in Perceptual and Cognitive Abilities. <i>Psychology and Marketing</i> . 1998;15(7):643-662.	
4522	1998	Rogers W, Rousseau G, Lamson N. Maximizing the Effectiveness of the Warning Process: Understanding the Variables that Interact with Age. In: Morrell R, Park D, eds. <i>Aging and Medication Information Processing</i> ; 1998.	

Exh No.	Date	Description	Defendants' Objections
4523	1999	Laughery K, Hammond A. Overview. In: Wogalter M, DeJoy D, Laughery K, eds. <i>Warnings and Risk Communication</i> . London/Philadelphia: Taylor and Francis;; 1999:3-12.	
4524	1999	Tennesen M. Before you play doctor. <i>Health</i> 1999:98-100,102-103.	
4525	1999	Braus P. Did you take your medicine? <i>American Demographics</i> . 1993:14-15.	
4526	2000	Garcia-Doval I, LeCleach L, Bocquet H, Otero X, Roujeau J. Toxic epidermal necrolysis and Stevens-Johnson Syndrome. <i>Archives of Dermatology</i> . 2000;136:323-327.	
4527	2000	Rogers W, Lamson N, Rousseau G. Warning research: An integrative perspective. <i>Human Factors</i> . 2000;42(1):102-139.	
4528	2000	Bastuji-Garin S, Fouchar N, Bertochii M, Roujeau J, Revuz J, Wolkenstein P. SCORTEN: A Severity-of-Illness Score for Toxic Epidermal Necrolysis. <i>The Society for Investigative Dermatology</i> . 2000;115(2):149-153.	
4529	2002	Gibertson W. Overview of Aspirin and NSAIDs Label Warnings. In: Products DoOD, ed. Vol. 2010; 2002.	
4530	2002	Auquier-Dunant A, Mockenhaupt M, Naldi L, al. e, SCAR Study Group. Correlations between clinical patterns and causes of erythema multiforme majus, Stevens-Johnson syndrome and toxic epidermal necrolysis: Results of an international prospective study. <i>Archives of Dermatology</i> . 2002;138(8):1019-1024.	
4531	2002	Wyeth Consumer Healthcare. Meeting Topic: NDAC Meeting on Risks of NSAIDs. 2002.	Lacks authentication (Rule 901)
4532	2003	Mockenhaupt M, Kelly J, Daufman D, Stern R. The risk of Stevens-Johnson Syndrom and Toxic Epidermal Necrolysis association with nonsteroidal antiinflammatory drugs: A multinational perspective. <i>The Journal of Rheumatology</i> . 2003;30(10):2234-2240.	
4533	2005	Food and Drug Administration. Supplemental Labeling Request- CBE. Vol. 2010. Rockville, MD; 2005.	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
4534	2006	French L. Toxic epidermal necrolysis and Stevens Johnson Syndrome: Our current understanding. <i>Allergology International</i> 2006;55:9-16.	
4535	2009	Merck. Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). In: Rehmus W, ed. <i>Merck online manual</i> . Vol. 2010; 2009.	
4536	2010	de la Fuente J, Bix L. A proposed framework for understanding human-package interactions. Packaging Technology and Science. East Lansing, MI: Michigan State University; 2010.	
4537	12/6/2010	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Royal Bunin	
4538	12/6/2010	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Everett Dillman, Ph. D.	
4539	12/6/2010	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Dr. Stephen Foster	
4539.1	2011	Supplement to Expert Report served 4.25.11	
4540	1922	Stevens AM, Johnson FC. A new eruptive fever associated with stomatitis and ophthalmia: report of two cases in children. <i>Am J Dis Child</i> . 1922;24:526-533.	
4541	1950	Thomas BA. The so-called Stevens-Johnson syndrome. <i>BMJ</i> .1950;1: 1393-1397.	
4542	1956	Lyell A. Toxic epidermal necrolysis: an eruption resembling scalding of the skin. <i>Br J Dermatol</i> . 1956;68:355-361.	
4543	1972	Stein KM, Schlappner LA, Heaton CL, et al. Demonstration of basal cell immunofluorescence in druginduced toxic epidermal necrolysis. <i>Br J Dermatol</i> . 1972;86:246-252.	
4544	1972	Pegram PS, Mountz JD, O'Bar P, Ro Ethambutol-induced toxic epidermal necrolysis. <i>Arch Intern Med</i> . 1972;141:1677-1678.	
4545	1972	Kauppinen, et al. Cutaneous Reactions to Drugs, A Clinical Study, <i>Acta Dermato-Venereologica</i> , Vol. 52, Supp. 68 (1972).	

Exh No.	Date	Description	Defendants' Objections
4546	1975	Bottiger LE, Strandberg I, Westerholm B. Drug induced febrile mucocutaneous syndrome. Acta Med Scand. 1975;198: 229-233.	
4547	1975	Bottiger LE, Strandberg I, Westerholm B. Drug induced febrile mucocutaneous syndrome. Acta Med Scand. 1975;198:229-233.	
4548	1975	Rasmussen JE. Toxic epidermal necrolysis: a review of 75 cases in children. Arch Dermatol. 1975;111:1135-1139.	
4549	1978	Sternlieb, P., et al., NY State Jour of Med, "Stevens-Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen," pp. 1239-43, 1978.	
4550	1979	Lyell A. Toxic epidermal necrolysis (the scalded skin syndrome): are-appraisal. Br 1 Dermatol. 1979;100:69-86.	
4551	1980	44 Yetiv JZ, Bianchine JR, Owen JA. Etiologic factors of the Stevens-Johnson syndrome. South Med J. 1980;73:599-602.	
4552	1980	Rasmussen JE. Toxic epidermal necrolysis. Med Clin North Am. 1980;64:901-920.	
4553	1982	Mondino BJ, Brown SI, Biglan A W, et al. HLA antigens in Stevens-Johnson syndrome with ocular involvement. Arch Ophthalmol. 1982;100:1453-1454.	
4554	1982	Hurwitz, Robert M.D., et al., J Am Acad Dermatol, "Toxic shock syndrome or toxic epidermal necrolysis?", 7:246-254, 1982.	
4555	1983	48 Schmidt D, Kluge W. Fatal toxic epidermal necrolysis following reexposure to phenytoin: a case report. Epilepsia. 1983; 24:440-443.	
4556	1984	De Groot R, Oranje AP, Vuzeski VD, et al. Toxic epidermal necrolysis probably due to Klebsiella pneumoniae sepsis. Dermatologica. 1984;169:88-90.	
4557	1985	Ruiz-Maldonado R. Acute disseminated epidermal necrosis types 1, 2, and 3: study of sixty cases. J Am Acad Dermatol. 1985;13:623-635.	
4558	1985	Hawk RJ, Storer JS, Daum RS. Toxic epidermal necrolysis in a 6-week year old infant. Pediatr Dermatol. 1985;2: 197-200.	

Exh No.	Date	Description	Defendants' Objections
4559	1985	O'Brien, W., et al., Jour of Rheumatology, "Rare Adverse Reactions to Nonsteroidal Anti-inflammatory Drugs," Vol. 12, No.1, pp. 13-17, 1985.	
4560	1987	Revuz J, Penso D, Roujeau JC, et al. Toxic epidermal necrolysis: clinical findings and prognosis factors in 87 patients. Arch Dermatol. 1987;123:1160-1165.	
4561	1987	Guillaume JC, Roujeau JC, Revuz J, et al. The culprit drugs in 87 cases of toxic epidermal necrolysis (Lyell's syndrome). Arch Dermatol. 1987;123: 1166-1170.	
4562	1987	Roujeau, J., Scand J Rheumatology, "Clinical Aspects of Skin Reactions to NSAIDs," Suppl. 65, pp. 131-4, 1987.	
4563	1988	Foster CS, Fong LP, Azar D, Kenyon KR. Episodic conjunctival inflammation after Stevens-Johnson Syndrome. Ophthalmology. Apr 1988;95(4):453-62.	
4564	1988	Dreyfuss DA, Gottlieb LJ, Wilkerson DK, et al. Survival after a second episode of toxic epidermal necrolysis. Ann Plast Surg. 1988;20: 146-147.	
4565	1990	Lyell A. Requiem for toxic epidermal necrolysis. Br J Dermatol.1990;122:837-846.	
4566	1990	Arnold HL Jr, Odom RB, James WD. Contact dermatitis; drug eruptions. In: Andrews' Diseases of the Skin: Clinical Dermatology. 8th ed. Philadelphia, PA: WB Saunders; 1990:128-130.	
4567	1990	Roujeau JC, Guillaume JC, Fabre JP, et al. Toxic epidermal necrolysis (Lyell syndrome): incidence and drug etiology in France, 1981-1985. Arch Dermatol. 1990;126:37-42.	
4568	1990	Roujeau JC, Chosidow O., Saiag P, et al. Toxic epidermal necrolysis (Lyell syndrome). Am Acad Dermatol. 1990;23:1039-1058.	
4569	1990	Chan HL, Stern RS, Arndt KA, et al. The incidence of erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis: a population-based study with particular reference to reactions caused by drugs among outpatients. Arch Dermatol. 1990;126:43-4.	

Exh No.	Date	Description	Defendants' Objections
4570	1990	Naldi L, Locati F, Marchesi L, et al. Incidence of toxic epidermal necrolysis in Italy. Arch Dermatol. 1990;126: 1103-1104.	
4571	1990	Roujeau JC, Guillaume JC, Fabre JP, et al. Toxic epidermal necrolysis (Lyell syndrome): incidence and drug etiology in France, 1981-1985. Arch Dermatol. 1990;126:37-42.	
4572	1990	Chan HL, Stern RS, Arndt KA, et al. The incidence of erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis: a population-based study with particular reference to reactions caused by drugs among outpatients. Arch Dermatol. 1990;126:43-4.	
4573	1990	Naldi L, Locati F, Marchesi L, et al. Incidence of toxic epidermal necrolysis in Italy. Arch Dermatol. 1990;126: 1103-1104.	
4574	1990	Roujeau JC, Guillaume JC, Fabre JP, et al. Toxic epidermal necrolysis (Lyell syndrome): incidence and drug etiology in France, 1981-1985. Arch Dermatol. 1990;126:37-42.	
4575	1990	Roujeau, et al., J. of the Amer. Acad. of Dermatology, "Continuing medical education, Toxic Epidermal Necrolysis (Lyell Syndrome)", Vol. 23, No. 6, Part 1; 1039-1058 (1990).	
4576	1991	Sakellariou G, Koukoudis P, Karpouzas J, et al. Plasma exchange (PE) treatment in drug-induced toxic epidermal necrolysis (TEN). Int J Artif Org. 1991;14:634-638.	
4577	1991	Schopf E, Stuhmer A, Rzany B, et al. Toxic epidermal necrolysis and Stevens-Johnson syndrome: an epidemiologic study from West Germany. Arch Dermatol. 1991;127:839-842.	
4578	1991	Strom BL, Carson JL, Halpern A. A population-based study of Stevens-Johnson syndrome: incidence and antecedent drug exposure. Arch Dermatol. 1991;127:831-838.	
4579	1991	Chan, et al. & Foster, JAMA, "Ocular Cicatricial Pemphigoid Occurring as a Sequela of Stevens-Johnson Syndrome", Vol. 266, No. 11; 1543-46 (1991).	

Exh No.	Date	Description	Defendants' Objections
4580	1992	Patterson R, Grammer L, Greenberger PA, et al. Stevens Johnson syndrome (SJS): effectiveness of corticosteroids in management and recurrent SJS. Allergy Proc. 1992; 13:89-95.	
4581	1992	Saiag P, Caumes E, Chosidow O., et al. Drug-induced toxic epidermal necrolysis (Lyell syndrome) in patients infected with the human immunodeficiency virus. J. Am Acad Dermatol. 1992;26:567-574.	
4582	1992	Holden, MD, J Postgraduate Medicine, "Over-the-counter medications: Do you know what your patients are taking?," Vol. 91, No. 81, June 1992.	
4583	1993	Bastuji-Garin S, Rzany B, Stern RS, Shear NH, Naldi L, Roujeau Je. Clinical classification of cases of toxic epidermal necrolysis, Stevens-Johnson syndrome, and erythema multiforme. Arch Dermatol. 1993;129:92-96.	
4584	1994	Roujeau J. The spectrum of Stevens-Johnson syndrome and toxic epidermal necrolysis: a clinical classification. J Invest Dermatol 1994;102: 28S-30S.	
4585	1994	Patterson R, Miller M, Kaplan M, et al. Effectiveness of early therapy with corticosteroids in Stevens- Johnson syndrome: experience with 41 cases and a hypothesis regarding pathogenesis. Ann Allergy. 1994;73:27-34.	
4586	1994	Kaufman DW. Epidemiologic approaches to the study of toxic epidermal necrolysis. J Invest Dermatol. 1994;102:31S-33S.	
4587	1994	Halpern, S., et al., et al., Arch Dermatology, "Cutaneous Toxicity of Ibuprofen," Vol. 130, pp. 259-260, Feb. 1994.	
4588	1994	Roujeau, J., et al., New England Jour of Med, "Severe Adverse Cutaneous Reactions to Drugs," Vol. 331, No. 19, pp. 1272-85, 1994.	
4589	1995	Assier H, Bastuji-Garin S, Revuz J, et al. Erythema multiforme with mucous membrane involvement and Stevens-Johnson syndrome are clinically different disorders with distinct causes. Arch Dermatol. 1995;131:539-543.	

Exh No.	Date	Description	Defendants' Objections
4590	1995	Roujeau JC, Kelly JP, Naldi L, et al. Medication use and the risk of Stevens-Johnson syndrome or toxic epidermal necrolysis. N Engl J Med. 1995;333:1600-1607.	
4591	1995	Roujeau, J., et al., New England Jour of Med, "Medication Use and the Risk of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis," Vol. 333, No. 24, pp. 1600-7, 1995.	
4592	1995	Power, W., et al., Ophthalmology, "Analysis of the Acute Ophthalmic Manifestations of the Erythema Multiforme/Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis Disease Spectrum," Vol. 102, No. 11, pp. 1669-76, 1995.	
4593	1995	Honig, PK et al., Drug Safety, "Drug Interactions Between Prescribed and Over-the-Counter Medication" 13 (5) 296-303 1995.	
4594	1996	Assier-Bonnet H, Aractingi S, Cadranel J, Wechsler J, Mayaud C, Saiag P. Stevens-Johnson syndrome induced by cyclophosphamide: report of two cases. Br J Dermatol. Nov 1996;135(5):864-6.	
4595	1996	McIvor RA, Zaidi J, Peters WJ, et al. Acute and chronic respiratory complications of toxic epidermal necrolysis. J Burn Care Rehabil. 1996;17:237-240.	
4596	1996	Rzany B, Hering O., Mockenhaupt M, et al. Histopathological and epidemiological characteristics of patients with erythema exudativum multi forme major, Stevens-Johnson syndrome and toxic epidermal necrolysis. Br J Dermatol. 1996; 135:6-11.	
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4598	1996	Stern and Shear, Cutaneous Medicine & Surgery, Chapter 43, pp. 412-425, 414, 1996.	

Exh No.	Date	Description	Defendants' Objections
4599	1997	Roujeau JC. Stevens-Johnson syndrome and toxic epidermal necrolysis are severity variants of the same disease which differs from erythema multiforme. J Dermatol. 1997;24: 726-729.	
4600	1997	Roujeau JC. Stevens-Johnson syndrome and toxic epidermal necrolysis are severity variants of the same disease which differs from erythema multiforme. J Dermatol. 1997;24: 726-729.	
4601	1997	Mockenhaupt, M., et al., Abstracts from the 1997 Annual Meeting International Dermatol Epidemiology Association, Abstract 28, "Risk Factors for Stevens-Johnson Syndrome(SJS) and Toxic Epidermal Necrolysis (TEN) Evaluation of Non-Steroidal Antiinflammatory Drugs (NSAIDS) and Muscle Relaxants," Vol. 108, No. 3, p. 367, 1997.	
4602	1997	Eisenberg, et al., Annals of Internal Medicine, "Advising Patients Who Seek Alternative Medical Therapies", Vol. 27, No. 1; 61-69 (1997).	
4603	1997	Eisenberg, et al., Annals of Internal Medicine, "Advising Patients Who Seek Alternative Medical Therapies", Vol. 27, No. 1; 61-69 (1997).	
4604	1998	Srivastava, M, et al, Gastroenterology, "Drug-Associated Acute – Onset Vanishing Bile Duct and Stevens-Johnson Syndrome in a Child," Vol. 115, pp. 743-746, 1998.	
4605	1998	Becker C, Barbulescu K, Hildner K, Meyer zum Buschenfelde KH, Neurath MF: Activation and methotrexate-mediated suppression of the TNF alpha promoter in T cells and macrophages. Ann N Y Acad Sci 859:311-314 (1998).	
4606	1998	Eisenberg, et al., JAMA, "Trends in Alternative Medicine Use in the United States, 1990-1997, Results of a Follow-up National Survey", Vol. 280, No. 18;15691-73 (1998).	
4607	1998	Eisenberg, et al., JAMA, "Trends in Alternative Medicine Use in the United States, 1990-1997, Results of a Follow-up National Survey", Vol. 280, No. 18;15691-73 (1998).	

Exh No.	Date	Description	Defendants' Objections
4608	1999	Sheridan, R., et al., Jour of Bum Care & Rehab, "A Management of Severe Toxic Epidermal Necrolysis in Children," pp. 497-500, 1999.	
4609	1999	Hensrud, et al., Mayo Clinic Proceedings, "Underreporting the Use of Dietary Supplements and Nonprescription Medications Among Patients Undergoing a Periodic Health Examination" 74:5, 443-448, 1999.	
4610	2000	Garcia DI, LeCleach L, Bocquet H, et al. Toxic epidermal necrolysis and Stevens-Johnson syndrome: does early withdrawal of causative drugs decrease the risk of death? Arch Dermatol. 2000; 136:323-327.	
4611	2000	Schluz, J.T., et al., A 10-Year Experience with Toxic Edipermal Necrolysis. J. Burn Care Rehabil. 2000; 21:199-204.	
4612	2000	Mockenhaupt, M, Roujeau, JC, et al., Antirheumatic Medication and the Risk for severe cutaneous reactions, ISPE-Poster presentation, 2000.	
4613	2001	Spies, M., et al., Pediatrics, "Treatment of Extensive Toxic Epidermal Necrolysis in Children," Vol. 108, pp. 1162-8, 2001.	
4614	2001	Majumdar S, Aggarwal BB: Methotrexate suppresses NfkappaB activation through inhibition of IkappaBalpalpha phosphorylation and degradation. J Immunol 167:2911-2920 (2001).	
4615	2001	Sullivan JR. Shear NH. The Drug Hypersensitivity Syndrome: What is the pathogenesis? Arch Dermatol, 137:357-364 (2001)(an article about Drug Hypersensitivity Syndrome from which SJS and TEN can result).	
4616	2001	Sleath, et al., Social Science & Medicine, "Physician-patient communication about over-the-counter medications", 53 (2001) 357-369.	
4617	2001	Sleath, et al., Social Science & Medicine, "Physician-patient communication about over-the-counter medications", 53 (2001) 357-369.	
4618	2002	Sheridan, R., et al, Pediatrics "Long Term Consequences of Toxic Epidermal Necrolysis in Children," pp. 109: 74-78, 2002.	

Exh No.	Date	Description	Defendants' Objections
4619	2002	Chan E. Cronstein B. Molecular action of methotrexate in inflammatory diseases. Arthritis Research 4:4:266-273 (2002).	
4620	2003	Ahmed AR, Dahl MV. Consensus statement on the use of intravenous immunoglobulin therapy in the treatment of autoimmune mucocutaneous blistering diseases. Arch Dermatol. Aug 2003;139(8):1051-9.	
4621	2003	Mockenhaupt M, Kelly JP, Kaufman D et al., for the SCAR Study Group "The risk of Stevens-Johnson syndrome and toxic epidermal necrolysis associated with nonsteroidal anti-inflammatory drugs: a multinational prospective". J Rheumatol. 2003; 30:2234-40.	
4622	2003	Roujeau, J., et al., Arch Dermatol, "Intravenous Immunoglobulin Treatment for Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis," Vol. 139, No. 1, pp. 33-36, 2003.	
4623	2004	Food and Drug Administration. "FDA issues public health advisory on Vioxx as its manufacturer voluntarily withdraws the product". www.fda.gov/bbs/topics/news/2004/NEW01122.html .	
4624	2004	<u>Food and Drug Administration. "FDA talk paper: Bextra label updated with boxed warning concerning severe skin reactions and warning regarding cardiovascular risk". www.fda.gov/bbs/topics/ANSWERS/2004/ANS01331.html.</u>	Lacks authentication (Rule 901)
4625	2004	Taghian, M., et al., Pediatrics, "Acute Vanishing Vile Duct Syndrome After Ibuprofen Therapy in a Child," pp. 273-6, 2004.	
4626	2004	Roumie, et al., Drugs Aging, "Over-the-Counter Analgesics in Older Adults, A Call for Improved Labeling and Consumer Education" 21(8), 485-98 (2004).	
4627	2004	Roumie, et al., Drugs Aging, "Over-the-Counter Analgesics in Older Adults, A Call for Improved Labeling and Consumer Education" 21(8), 485-98 (2004).	

Exh No.	Date	Description	Defendants' Objections
4628	2006	French LE. Toxic epidermal necrolysis and Stevens Johnson syndrome: our current understanding. Allergol Int. Mar 2006;55(1):9-16.	
4629	2006	French LE, Trent JT, Kerdel FA. Use of intravenous immunoglobulin in toxic epidermal necrolysis and Stevens-Johnson syndrome: our current understanding. Int Immunopharmacol. Apr 2006;6(4):543-9.	
4630	2006	Gardiner, et al., Arch Intern Med., "Factors Associated With Dietary Supplement Use Among Prescription Medication Users" 166:1968-1974, 2006.	
4631	2007	De Rojas MV, Dart JK, Saw VP. The natural history of Stevens Johnson syndrome: patterns of chronic ocular disease and the role of systemic immunosuppressive therapy. Br J Ophthalmol. Aug 2007; 91(8): 1048-53.	
4632	2007	De Rojas MV, Dart JK, Saw VP. The natural history of Stevens Johnson syndrome: patterns of chronic ocular disease and the role of systemic immunosuppressive therapy. Br J Ophthalmol. Aug 2007; 91(8): 1048-53.	
4633	2009	Levi, N, et al., Pediatrics, "Medications as Risk Factors of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Children: A Pooled Analysis," 123(2) e297-304, 2009.	
4634	No date	Food and Drug Administration. "Alert for healthcare professionals: celecoxib (marketed as Celebrex)". www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.pdf.	
4635	No date	Food and Drug Administration, Information for Patients and Providers, www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM103420	Lacks authentication (Rule 901)
4636	12/6/2010	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Marvin Goldberg, Ph.D.	

Exh No.	Date	Description	Defendants' Objections
4636.1	7/3/1905	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Marvin Goldberg, Ph.D. as produced and relied on or published to the jury in the Maya, et ux. v. J&J, et al, case	
4637	12/6/2010	Appendix A to the Report of Marvin Goldberg, Ph.D. - Reliance List	
4638	12/6/2010	McNeil Children's Motrin & Children's Tylenol Advertizing Materials as produced and published in the Maya case (identified there as Exhibits 4510 and 4510.1-4510.10)	Lacks authentication (Rule 901)
4639	12/6/2010	Appendix B to the Report of Marvin Goldberg, Ph.D. - Curriculum Vitae	
4640	6/3/1905	Ross, Kenneth, 1981, "Legal and Practical Considerations for the Creation of Warning Labels and Instruction Books," Journal of Products Liability, 4, 29-45	
4641	1987	Wogalter, MS, Godfrey SS, Fontenelle, GA, Desaulniers, DR, Rothstein, PR and Laughery, KR (1987) "Effectiveness of warnings." Human Factors, 29, 599-612; (see reference to this finding in Wogalter, MS, DeJoy, DM and Laughery, KR (eds.) (1999) "Warnings and Risk Communication," Taylor & Francis: London, Philadelphia).	
4642	1989	Retail Marketing Materials (2: 1989; MC069466	Lacks authentication (Rule 901)
4643	1989	Sales Training Material: 3: 7/28/89; Pediaprofen Product Information; MC069438	Lacks authentication (Rule 901)
4644	1989	Sales Training Material: (3: 7/28/89); Pediaprofen Product Information MC069433	Lacks authentication (Rule 901)
4645	1991	Wogalter, MS. et al. (1991) "Consumer Product Warnings: The Role of Hazard Perception," Journal of Safety Research, 22, 71-82).	
4646	1995	Lesko, SM & Mitchell, AA, (1995) "An Assessment of the Safety of Pediatric Ibuprofen: A Practitioner-Based Randomized Clinical Trial." JAMA, 273(12): 929-933.	
4647	1995	Marketing Research (1: 1989-95; MOT00007611 - 14	Lacks authentication (Rule 901)
4648	1995	FDA clears Children's Motrin for OTC Marketing; 6/19/95; MOT00007644 - 54	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
4649	1995	Children"s Motrin Marketing exclusivity 12/7/95; 1599-1603	Lacks authentication (Rule 901)
4650	1995	Children's Motrin Marketing exclusivity 12/7/95; MC071597 -9	Lacks authentication (Rule 901)
4651	1996	Parents Magazine, January, March 1996	Lacks authentication (Rule 901)
4652	2001	Children's Tylenol and Children's Motrin Pediatric; First Quarter 2001; MC073802 -9).	
4653	2001	"Children"s Tylenol and Children"s Motrin; Pediatric; 1st Quarter 2001; MCO73816 - 23	
4654	2002	National Council on Patient Information and Education (NCPIE) 2002 "Attitudes and Belief	
4655	2002	Rosenthal, MB, Berndt, ER, Donohue, JM, Frank, RG, Epstein, AM (2002) "Promotion o f Prescription Drugs to Consumers," New England Journal of Medicine, Vol. 346 (7); 498-505.	
4656	2002	NCPIE 2002.	Lacks authentication (Rule 901)
4657	2003	Gahart, MT, Duhamel, LM, Dievier, A, Price R. (2003) "Examining the FDA"s of Direct-To-Consumer Advertising," Health Affairs, w3-120-123.	
4658	2005	FDA letter of June 22, 2005, to Roger E. Salisbury MD.	
4659	2006	Brennan et al. (2006) "Health Industry Practices That Create Conflicts of Interest, JAMA (Jan. 23) 429-433.	
4660	2006	Vredenburg, AG & Zackowitz, IB, "Expectations;" Ch. 25 in MS Wogalter, ed. (2006)	
4661	2008	Association of American Medical Colleges (AAMC) "Industry Funding of Medical Education; Report of an AAMC Task Force," (2008); www.aamc.org/publications	
4662	No date	About the Use of Over-the-Counter Medicines: A Dose of Reality; A National Survey of Consumers and Health Professionals" www.harrisinteractive.com	
4663	No date	"Handbook of Warnings," Lawrence Erlbaum Associates: Mahwah NJ, London.	
4664	No date	MOT00007670	

Exh No.	Date	Description	Defendants' Objections
4665	No date	Sales Materials MOT00007664 - 7745	Lacks authentication (Rule 901)
4666	No date	Product and Sales Backgrounder; MC072319 - 20	Lacks authentication (Rule 901)
4667	No date	An exploration of dual usage of CT and CM. MOT00059325	Lacks authentication (Rule 901)
4668	No date	An Exploration of Dual Usage of CT and CM; MOT00059319/25	Lacks authentication (Rule 901)
4669	No date	"It Takes Two" MC040881	Lacks authentication (Rule 901)
4670	No date	Year one results; MOT00009319-20; also MOT00007667 - 7745	Lacks authentication (Rule 901)
4671	No date	"Leadership takes Many Forms:" Professional Sales Material;" MOT00009433 - 9541	Lacks authentication (Rule 901)
4672	No date	MC069393-4	Lacks authentication (Rule 901)
4673	No date	"Sales Materials" Year 1 results; MOT00007665 - 7	Lacks authentication (Rule 901)
4674	No date	Letter from DDMAC MCO63664; re Motrin sales aide materials MCO63668 - 76	
4675	No date	Letter from DDMAC MCO63713 - 6	
4676	No date	MOT00007647	
4677	12/6/2010	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Carol Hyland, M.A., M.S., C.D.M.S., C.L.C.P.	
4678	12/10/2010	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Dr. Chirag Parikh	
4679	12/6/2010	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Dr. John Schulz	
4679.1	2011	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Dr. John Schulz as produced and relied on in the Maya, et ux. v. J&J, et al. case.	
4679.2	2011	Supplement to Expert Report served 4.25.11	
4680	12/6/2010	Expert Report of Dr. John Schulz Exhibit 1 - Curriculum Vitae	
4681	No date	Expert Report of Dr. John Schulz Exhibit 2 - What Causes TEN? Index	
4682	2006	Expert Report of Dr. John Schulz Exhibit 3 - Motrin Label and Medication Guide Dated January 2006	

Exh No.	Date	Description	Defendants' Objections
4683	No date	Expert Report of Dr. John Schulz Exhibit 4 - Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	
4684	2000	Expert Report of Dr. John Schulz Exhibit 5 - Box labeling for Children's Motrin Oral Suspension, Berry Flavored 2000	
4685	2001	Expert Report of Dr. John Schulz Exhibit 6 - Box labeling for Children's Motrin Oral Suspension, Grape Flavored 2001	
4686	2005	Expert Report of Dr. John Schulz Exhibit 7 - Certification of and Citizen Petition 2005-P-130 (formerly 2005P-0072) 2/15/2005	
4687	2005	Expert Report of Dr. John Schulz Exhibit 8 - 4/6/05 Memorandum from FDA re: Analysis and recommendations for Agency action regarding nonsteroidal anti-inflammatory drugs and cardiovascular risk	
4688	2005	Expert Report of Dr. John Schulz Exhibit 9 - 4/7/05 FDA News Release: FDA Announces Series of Changes to the Class of Marketed Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	
4689	2005	Expert Report of Dr. John Schulz Exhibit 10 - FDA Public Health Advisory: FDA Announces Important Changes and Additional Warnings for COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). 4/7/05	
4690	2005	Expert Report of Dr. John Schulz Exhibit 11 - FDA Postmarket Drug Safety Information for Patients and Providers: COX-2 Selective (includes Bextra, Celebrex, and Vioxx) and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). 4/7/05	
4691	2005	Expert Report of Dr. John Schulz Exhibit 12 - SUPPLEMENTAL LABELING REQUEST - CBE Template	
4692	2006	Expert Report of Dr. John Schulz Exhibit 13 - DHHS 6/22/06 Letter to Dr. Salisbury re: 2/15/05 Citizen Petition.	

Exh No.	Date	Description	Defendants' Objections
4693	2009	Expert Report of Dr. John Schulz Exhibit 14 - McNeil BRIEFING MATERIALS FOR DRUG SAFETY AND RISK MANAGEMENT ANESTHETIC AND LIFE SUPPORT AND NONPRESCRIPTION DRUGS ADVISORY COMMITTEE MEETING JUNE 29-30, 2009	Lacks authentication (Rule 901)
4694	No date	Expert Report of Dr. John Schulz Exhibit 15 - Villalta, P., "Toxic Epidermal Necrolysis'TEN': A Case Report," Powerpoint Presentation regarding Tiffany Persaud.	
4695	1991	Expert Report of Dr. John Schulz Exhibit 16 - Patient Data Listing for Sutdy 90-056: Children's Motrin Ibuprofen Suspension 1991	
4696	1991	Expert Report of Dr. John Schulz Exhibit 17 - Patient Data Listing for Sutdy 90-056: Children's Motrin Ibuprofen Suspension 1991	
4697	1995	Expert Report of Dr. John Schulz Exhibit 18 - Statistical Review and Evaluation. NDA 20-516. 2/27/1995	
4698	1994	Expert Report of Dr. John Schulz Exhibit 19 - 1994 PDR Label for Motrin	
4699	2004	Expert Report of Dr. John Schulz Exhibit 20 - 21 CFR § 201.56	
4700	2005	Expert Report of Dr. John Schulz Exhibit 21 - 21 C.F.R. § 201.57	
4701	2005	Expert Report of Dr. John Schulz Exhibit 22 - 21 C.F.R. § 314.80	
4702	1995	Expert Report of Dr. John Schulz Exhibit 23 - 1995 PDR Label for Motrin	
4703	1995	Expert Report of Dr. John Schulz Exhibit 24 - 1995 PDR Label for Children's Motrin	
4704	1998	Expert Report of Dr. John Schulz Exhibit 25 - 1998 PDR Label for Motrin	
4705	2008	Expert Report of Dr. John Schulz Exhibit 26 - FDA Drug Safety Newsletter Winter 2008	
4706	1998	Expert Report of Dr. John Schulz Exhibit 27 - 1998 PDR Label for Motrin	
4707	1999	Expert Report of Dr. John Schulz Exhibit 28 - 1999 PDR Label for Motrin	
4708	2000	Expert Report of Dr. John Schulz Exhibit 29 - 2000 PDR Label for Motrin	

Exh No.	Date	Description	Defendants' Objections
4709	2001	Expert Report of Dr. John Schulz Exhibit 30 - 2001 PDR Label for Motrin	
4710	No date	Expert Report of Dr. John Schulz Exhibit 31 - 20 DRUGS WITHDRAWN FROM THE MARKET BASED ON CASE REPORTS OR SERIES WITH NO CASE CONTROL STUDIES Index and Citations	Lacks authentication (Rule 901)
4711	1984	Expert Report of Dr. John Schulz Exhibit 32 - McNeil Petition for Reconsideration 6/18/1984	Lacks authentication (Rule 901)
4712	1984	Expert Report of Dr. John Schulz Exhibit 33 - McNeil Summary Basis for Approval. 5/31/1984	Lacks authentication (Rule 901)
4713	1984	Expert Report of Dr. John Schulz Exhibit 34 - FDC Reports 46(13): T&G-I (March 26) 1984: Trade and Government Memos: OTC Ibuprofen Labeling Based on Rx Package Insert Information.	Lacks authentication (Rule 901)
4714	1972	Kauppinen K. Cutaneous Reactions to Drugs, A Clinical Study, Acta Dermato-Venereologica, 1972 Vol. 52, Supp. 68	
4715	1978	Sternlieb P. Robinson RM. Stevens Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen. NY State J Med July 1978. pp 1239-1243	
4716	1978	Sternlieb P. Robinson RM. Stevens Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen. NY State J Med July 1978. pp 1239-1243	
4717	1982	Hurwitz RM. Rivera HP. Gooch MH. Slama TG. Handt A. Weiss J. Toxic shock syndrome or toxic epidermal necrolysis. J Am Acad Dermatol 1982. 7:246-254.	
4718	1983	Schmidt D. and Kluge W. Fatal Toxic Epidermal Necrolysis Following Reexposure to Phenytoin: A Case Report. Epilepsia 1983. 24:440-443.	
4719	1984	Wintroub, B. U., et al., Cutaneous Reactions to Drugs. Current Perspectives in Immunodermatology 1984 75-97 (MacKie, R. M. (ed) Churchill Livingstone).	
4720	1985	O'Brien WM. Bagby JF. Rare Adverse Reactions of Nonsteroidal Antiinflammatory Drugs. J Rheumatol 1985. 12:13-20.	

Exh No.	Date	Description	Defendants' Objections
4721	1985	Bigby M. Stern R. Cutaneous reactions to nonsteroidal anti-inflammatory drugs. J Am Acad Dermatol 1985. 12:866-876.	
4722	1987	Roujeau JC. Clinical Aspects of Skin Reactions to NSAIDs. Scand J Rheumatology 1987. (Suppl. 65): 131-134	
4723	1988	Delattre JY. Safai B. Posner JB. Erythema multiforme and Stevens-Johnson Syndrome in patients receiving cranial irradiation and phenytoin. Neurology 1988. 38:194-8	
4724	1989	Bigby, Stern, R., et al., Allergic Cutaneous Reactions to Drugs. Primay Care 1989 16(3) 713-727	
4725	1989	Stern, R. S., et al. Adverse Cutaneous reactions to Nonsteroidal Anti-Inflammatory Drugs. Pharm. Skin 1989 148-156 (Hensby, C., et al. (eds.) Basel Karger	
4726	1989	Stern, R. S., et al. Usefulness of Case report Literature in Determining Drugs Repsonsible for Toxic Epidermal Necrolysis. J. Amer. Acad. Derm 1989 21(2) 317-322	
4727	1989	Stern RS. Wintroub BU. Adverse Cutaneous Reactions to Nonsteroidal Anti-Inflammatory Drugs. Hensby C. Lowe NJ (eds): Nonsteroidal Anti-Inflammaroty Drugs. Pharmacol Skin. Basel. Karger. Vol 2:148-156. 1989	
4728	1990	Roujeau JC. Toxic Epidermal Necrolysis (Lyell syndrome) Arch Dermatol (1990)126:37- 42	
4729	1990	Roujeau JC. Guillaume JC. Fabre JP. Penso D. Flechet ML. Girre JP. Toxic Epidermal Necrolysis. Arch Dermatol 1990. 126:37-42	
4730	1990	Roujeau JC., et al. Continuing medical education, Toxic Epidermal Necrolysis (Lyell Syndrome), J. of the Amer. Acad. of Dermatology. 1990. 23, No. 6, Part 1; 1039-1058	
4731	1990	Roujeau JC. Chosidow O. Saiad P. Guillaume JC. Toxic epidermal necrolysis (Lyell syndrome). J Am Acad Dermatol 1990. 23:1039-1038.	
4732	1992	Holden MD. Over-the-counter medications: Do you know what your patients are taking? J Postgraduate Medicine (1992) 91(81).	
4733	1992	Parsons JM. Toxic Epidermal Necrolysis. Int J Dermatol 1992. 31:749-768.	

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4734	1993	Halpern SM. Fitzpatrick R. Volans GN. Ibuprofen toxicity. A review of adverse reactions and overdose. Adverse Drug React Toxicol Rev 1993. 12(2):107-128.	
4735	1994	Halpern M. Volans GN. Cutaneous Toxicity of Ibuprofen. Arch Dermatol 1994. 130:259- 260.	
4736	1994	Roujeau JC. Stern RS. Severe Adverse Cutaneous Reactions to Drugs. New England J Med 1994. 331:1272-1285.	
4737	1995	Honig PK et al. Drug Interactions Between Prescribed and Over-the-Counter Medication. Drug Safety (1995) 13(5): 296-303.	
4738	1995	Roujeau J-C. et al. Medication Use and the Risk of Stevens Johnson Syndrome or Toxic Epidermal Necrolysis. N Engl J Med 1995. 333:1600-7	
4739	1995	Sharma, V. K., et al., Clinical Pattern of Cutaneous Drug Eruption Among Children and Adolescents in North India. Ped. Derm. 1995 12(2) 178-183	
4740	1995	Roujeau JC. Kelly JP. Naldi L. Rzany B. Stern RS. Anderson T. Auquier A. Basuji-Garin S. Correia O. Locati F. Mockenhaupt M. Paoletti C. Shapiro S. Shear N. Schopf E. Kaufman DW. Medication Use and the Risk of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis. New Eng J Med 1995. 333:1600-1607.	
4741	1995	Power WJ. Ghoraishi M. Merayo-Llodes J. Neves RA. Foster S. Analysis of the Acute Ophthalmic Manifestations of the Erythema Multiforme/Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis Disease Spectrum. Ophthalmology 1995. 102:1669-1676.	
4742	1995	Lesko SM. Mitchell AA. An Assessment of the Safety of Pediatric Ibuprofen. JAMA 1995. 273:929-933.	
4743	1996	Cockey GH. Amann ST. Reents SB. Lynch JW Jr. Stevens-Johnson syndrome resulting from whole-brain radiation and phenytoin. Am J Clin Oncol 1996 Feb. 19(1):32-4.	

Exh No.	Date	Description	Defendants' Objections
4744	1996	Khoo, A. K. M., at al., Toxic Epidermal Necrolysis in a Burns Centre: A 6-Year Review. Burns 1996 22(4) 275-278	
4745	1996	Stern R. Shear N. Cutaneous Medicine & Surgery, 1996 Chapter 43, pp. 412-425, 414	
4746	1996	Alam I. Ferrell LD. Bass NM. Vanishing Bile Duct Syndrome Temporally Associated with Ibuprofen Use. Am J Gastroenterol 1996. 91:1626-1630.	
4747	1997	Salomon D. French L-E. de Viragh P-A. Guggisberg D. Massouye I. Pechere M. Pugin J. Panizzon R. Saurat J-H. Five Cases of Toxic Epidermal Necrolysis Treated by Intravenous Immunoglobulins with Favorable Results. Ann Dermatol Venereol 1997. 124 (Suppl.): S216-S217.	
4748	1997	Lebargy F. Wolkenstein P. Gisselbrecht M. Lange F. Fleury-Feith J. Delclaux C. Roupie E. Revuz J. Roujeau JC. Pulmonary complications in toxic epidermal necrolysis: a prospective clinical study. Intensive Care Med 1997. 23:1237-1244.	
4749	1998	Becker C. et al. Activation and Methotrexate-Mediated Suppression of the TNFalpha Promoter in T Cells and Macrophages. Ann NY Acad Science. INTESTINAL PLASTICITY IN HEALTH AND DISEASE. 1998 859: 311-314.	
4750	1998	Wolkenstein PE. Roujeau JC. Revuz J. Drug-Induced Toxic Epidermal Necrolysis. Clin Dermatol 1998. 16:399-409.	
4751	1998	Wolkenstein PE. Roujeau JC. Revuz J. Drug-Induced Toxic Epidermal Necrolysis. Clin Dermatol 1998. 16:399-409.	
4752	1998	Viard I. Wehrli P. Bullani R. Schneider P. Holler N. Salomon D. Hunziker T. Sauret J-J. Tschopp J. French LE. Inhibition of Toxic Epidermal Necrolysis by Blockade of DC95 with Human Intravenous Immunoglobulin. Science 1998. 282:490-493.	

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4753	1998	Srivastava M. Perez-Atayde A. Jonas MM. Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child. Gastroenterology 1998. 115:743-746.	
4754	1999	Hensrud et al. Underreporting the Use of Dietary Supplements and Nonprescription Medications Among Patients Undergoing a Periodic Health Examination. Mayo Clinic Proceedings (1999) 74(5): 443-448.	
4755	1999	Khafaga YM. Jamshed A. Allam AA. Mourad WA. Ezzat A. Al Eisa A. Gray AJ. Schultz H. Stevens- Johnson syndrome in patients on phenytoin and cranial radiotherapy. Acta Oncologica 1999. 38:111-116	
4756	1999	Paul, C. N., et al. Case Report: Oxaprozin and Fatal Toxic Epidermal Necrolysis. J Burn Care & Rehab 1999 19(4) 321-323	
4757	1999	Sheridan RL. Weber JM. Schulz JT. Ryan CM. Low HM. Tompkins RG. Management of Severe Toxic Epidermal Necrolysis in Children. J Burn Care Rehabil 1999. 20:497-500	
4758	1999	Sheridan RL. Weber JM. Schulz JT. Ryan CM. Low HM. Tompkins RG. Management of Severe Toxic Epidermal Necrolysis in Children. J Burn Care Rehabil 1999. 20:497-500.	
4759	2000	Bastuji-Garin S. Fouchard N. Bertocchi M. et al. SCORTEN: a severity-of-illness score for toxic epidermal necrolysis. J Invest Dermatol 2000 (Aug) pp. 149–53	
4760	2000	Garcia-Doval I. LeCleach L. Bocquet H. Otero XL. Roujeau JC. Toxic epidermal necrolysis and Stevens-Johnson syndrome: does early withdrawal of causative drugs decrease the risk of death? Arch Dermatol 2000. 136:232-27	
4761	2000	Naisbitt, D. J., et al. Immunological Principles of Adverse Drug Reactions: The Initiation and Propagation of Immune Responses Elicited by Drug Treatment. Drug Safety 2000 23(6) 483-507	
4762	2000	Schulz JT. Sheridan RL. Ryan CM. MacKool B. Tompkins RG. A 10-Year Experience with Toxic Epidermal Necrolysis. J Burn Care Rehabil 2000. 21:199-204	

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4763	2000	Garcia-Doval I. LeCleach L. Bocquet H. Otero X-L. Roujeau JC. Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome. Arch Dermatol 2000. 136:323-327.	
4764	2001	Sleath et al. Physician-patient communication about over-the-counter medications. Social Science & Medicine (2001) 53:357-369.	
4765	2001	Eralp Y. Aydiner A. Tas F. Salp P. Topuz E. Stevens-Johnson syndrome in a patient receiving anticonvulsant therapy during cranial irradiation. AM J Clin Oncol 2001. 24:347-350	
4766	2001	Honari S. Gibran NS. Heimbach DM. Gibbons J. Cain V. Engrav LH. Toxic Epidermal Necrolysis (TEN) in Elderly Patients. J Burn Care Rehabil 2001. 22:132-135	
4767	2001	Spies M. Sanford AP. Low JFA. Wolf SE. Herndon DN. Treatment of Extensive Toxic Epidermal Necrolysis in Children. Pediatrics 2001. 108:1162-1168.	
4768	2001	Morelli MS. O'Brien FX. Stevens-Johnson Syndrome and Cholestatic Hepatitis. Digestive Diseases and Sciences 2001. 46:2385-2388.	
4769	2002	Chan E. Cronstein B. Molecular action of methotrexate in inflammatory diseases. Arthritis Research 2002, 4:4:266-273	
4770	2002	Nassif A. Bensussan A. Dorothee G. Mami-Chouaib F. Bachot N. Bagot M. Boumsell L. Roujeau JC. Drug specific cytotoxic T-cells in the skin lesions of a patient with toxic epidermal necrolysis. J Invest Dermatol 2002. 118:728-33	
4771	2002	Palmieri T. et al. A Multicenter Review of Toxic Epidermal Necrolysis Treated in U.S. Burn Centers at the End of the Twentieth Century. J Burn Care Rehabil 2002. 23: 87-96)	
4772	2002	Sheridan RL. Schulz JT. Ryan CM. Schnitzer JJ. Lawlor D. Driscoll DN. Donelan MB. Tompkins RG. Long-Term Consequences of Toxic Epidermal Necrolysis in Children. Pediatrics 2002. 109:74-78.	

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4773	2003	Mockenhaupt M. Kelly JP. Kaufman D. Stern RS. The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Antiinflammatory Drugs: a Multinational Perspective. J Rheumatol 2003. 30:2234-2240.	
4774	2003	Mockenhaupt M. Kelly JP. Kaufman D. Stern RS. The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Antiinflammatory Drugs: a Multinational Perspective. J Rheumatol 2003. 30:2234-2240.	
4775	2003	Prins C. Vittorio C. Padilla RS. Hunziker T. Itin P. Forster J. Brocker E-B. Saurat J-H. French LE. Effect of High Dose Immunoglobulin Therapy in Stevens-Johnson Syndrome: A Retrospective, Multicenter Study. Dermatology 2003; 207: 96-99.	
4776	2003	Prins C. Kerdel FA. Padilla S. Hunziker T. Chimenti S. Viard I. Mauri DN. Flynn K. Trent J. Margolis DJ. Saurat J-H. French LE. Treatment of Toxic Epidermal Necrolysis with High-Dose Intravenous Immunoglobulins. Arch Dermatol 2003; 139: 26-32.	
4777	2003	Bachot N. Revuz J. Roujeau JC. Intravenous Immunoglobulin Treatment for Stevens- Johnson Syndrome and Toxic Epidermal Necrolysis: a prospective noncomparative study showing no benefit on mortality or progression. Arch Dermatol 2003; 139: 33-36.	
4778	2004	Roumie et al. Over-the-Counter Analgesics in Older Adults, A Call for Improved Labeling and Consumer Education. Drugs Aging (2004) 21(8): 485-98	
4779	2004	Nassif A. Bensussan A. Boumsell L. Deniaud A. Moslehi H. Wolkenstein P. Bagot M. Roujeau JC. Toxic epidermal necrolysis: effector cells are drug-specific cytotoxic T cells.. J Allergy Clin Immunol 2004 Nov. 114(5):1209-15	
4780	2004	Taghian M. Tran TA. Besson-Hadni S. Menget A. Felix S. Jacquemin E. Acute Vanishing Bile Duct Syndrome After Ibuprofen Therapy in a Child. J Pediatr 2004. 145:273-276.	

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4781	2004	Taghian M. Tran TA. Besson-Hadni S. Menget A. Felix S. Jacquemin E. Acute Vanishing Bile Duct Syndrome After Ibuprofen Therapy in a Child. J Pediatr 2004. 145:273-276.	
4782	2005	Faye O. Roujeau JC. Treatment of epidermal necrolysis with high-dose intravenous immunoglobulins (IV Ig): clinical experience to date. Drugs 2005. 65(15):2085-90	
4783	2005	Lin M-S. Dai Y-S. Pwu R-F, Chen Y-H. Chang N-C. Risk estimates for drugs suspected of being associated with Stevens-Johnson syndrome and toxic epidermal necrolysis: a case-control study. Internal Medicine Journal 2005. 35:188-190	
4784	2005	Mockenhaupt M. Messenheimer J. Tennis P. Schlingmann J. Risk of Stevens-Johnson syndrome and toxic epidermal necrolysis in new users of anti-epileptics. Neurology 2005. 64:1134-1138	
4785	2005	Paquet P. Jacob E. Pierard GE. Cystic lesion of the parotid following drug-induced toxic epidermal necrolysis (Lyell's syndrome). J Oral Pathol Med 2005. 34:380-382.	
4786	2005	Paquet P. Jacob E. Pierard GE. Cystic lesion of the parotid following drug-induced toxic epidermal necrolysis (Lyell's syndrome). J Oral Pathol Med 2005. 34:380-382.	
4787	2005	Kim JK. Lee KP. Suh HS. Lee MW. Choi JH. Moon KC. Koh JK. Toxic Epidermal Necrolysis: Analysis of Clinical Course and SCORTEN-based Comparison of Mortality Rate and Treatment Modalities for Korean Patients. Acta Dermatol Venereol 2005; 85: 497-502.	
4788	2006	Gardiner et al. Factors Associated With Dietary Supplement Use Among Prescription Medication Users. Arch Intern Med (2006) 166:1968-1974.	
4789	2006	Imahara SD. Holmes JH 4th. Heimbach DM. Engrav LE. Honari S. Klein MB. Gibran NS. SCORTEN overestimates mortality in the setting of a standardized treatment protocol. J Burn Care Res 2006 May-Jun. 27(3):270-5	

Exh No.	Date	Description	Defendants' Objections
4790	2006	Oplatek A. Brown K. Sen S. Halerz M. Supple K. Gamelli RL. Long-term follow-up of patients treated for toxic epidermal necrolysis. J Burn Care Res 2006 Jan-Feb. 27(1):26-33	
4791	2007	Dore J. Salisbury RE. Morbidity and Mortality of Mucocutaneous Diseases in the Pediatric Population at a Tertiary Care Center. J Burn Care Research 2007. 28:865-870.	
4792	2007	Raksha, M. P., et al., Clinical Study of Cutaneous Drug Eruption in 200 Patients. Indian J Dermatol Venereol Leprol 2007 74(80) 80-84	
4793	2007	Tandon A. Cackett P. Mulvihill A. Fleck B. Amniotic membrane grafting for conjunctival and lid surface disease in the acute phase of toxic epidermal necrolysis. J AAPOS. 2007 Dec. 11(6):612- 613.	
4794	2007	Yamane Y. Aihara M. Ikezawa Z. Analysis of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Japan from 2000 to 2006. Allergol Internatl 2007; 56: 419-425.	
4795	2007	Yawalkar, N., Maculopapular Drug Eruptions. Drug Hypersensitivity 2007 242-250 (Pichler, W.J. (ed.) Basel, Karger	
4796	2007	Neuman M. Nicar M. Apoptosis in ibuprofen-induced Stevens-Johnson syndrome. Translational Research 2007. 149:254-259.	
4797	2007	Dore J. Salisbury RE. Morbidity and Mortality of Mucocutaneous Diseases in the Pediatric Population at a Tertiary Care Center. J Burn Care Res 2007. 28:865-870	
4798	2007	Yamane Y. Aihara M. Ikezawa Z. Analysis of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Japan from 2000 to 2006. Allergol Internatl 2007; 56: 419-425.	
4799	2008	Abood GJ. Nickloff BJ. Gamelli RL. Treatment strategies in toxic epidermal necrolysis syndrome: where are we at? J Burn Care Res 2008 Jan-Feb. 29(1):269-76	
4800	2008	Cartotto R. Mayich M. Nickerson D. Gomez M. SCORTEN accurately predicts mortality among toxic epidermal necrolysis patients treated in a burn center. J Burn Care Res 2008 Jan-Feb. 29(1):141-6	

Exh No.	Date	Description	Defendants' Objections
4801	2008	Chung WH. Hung SI. Yang JY. Su SC, Huang SP. Wei CY. Chin SW. Chiou CC. Chu SC. Ho HC. Yang CH. Lu CF. Wu JY. Liao YD. Chen YT. Granulysin is a key mediator for disseminated keratinocyte death in Stevens-Johnson syndrome and toxic epidermal necrolysis Nat Med 2008 Dec.14(12):1343-50. Epub 2008 Nov 23	
4802	2008	Endorf FW. Cancio LC. Gibran NS. Toxic epidermal necrolysis clinical guidelines. J Burn Care Res 2008 Sep-Oct. 29(5):706-12	
4803	2008	Ferrell PB. Carbamazepine, HLA-B*1502 and risk of Stevens-Johnson syndrome and toxic epidermal necrolysis: US FDA recommendations. Pharmacogenomics 2008. 9(10):1543-1546.	
4804	2008	Gregory DG. The ophthalmologic management of acute Stevens-Johnson syndrome. Ocul Surf 2008 Apr. 6(2):87-95	
4805	2008	Mayes T. Gottschlich M. Khoury J. Warner P. Kagan R. Energy requirements of pediatric patients with Stevens-Johnson syndrome and toxic epidermal necrolysis. Nutr Clin Pract 2008 Oct-Nov. 23(5):547-50	
4806	2008	Mockenhaupt M. Viboud C. Dunant A. Naldi L. Halevy S. Bouwes Bavinck JN. Sidoroff A. Schneck J. Roujeau JC. Flahault A. Stevens-Johnson syndrome and toxic epidermal necrolysis: assessment of medication risks with emphasis on recently marketed drugs. The EuroSCARstudy. J Invest Dermatol 2008 Jan. 128(1):35-44	
4807	2008	Murata J. Abe R. Shimizu H. Increased soluble Fas ligand levels in patients with Stevens-Johnson syndrome and toxic epidermal necrolysis preceding skin detachment. J Allergy Clin Immunol 2008 Nov. 122(5):992-1000	
4808	2008	Sharma VK. Sethuraman G. Minz A. Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and SJS-TEN overlap: A retrospective study of causative drugs and clinical outcome. Indian J Dermatol Venereol Leprol 2008. 74:238-40	

Exh No.	Date	Description	Defendants' Objections
4809	2008	Mockenhaupt M. Viboud C. Dunant A. Naldi L. Halevy S. Bavinck JNB. Sidoroff A. Schneck J. Roujeau JC. Flahault A. Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: Assessment of the Medication Risks with Emphasis on Recently Marketed Drugs. The EuroSCAR-Study. J Invest Dermatol 2008. 128:35-44.	
4810	2008	Raksha MP. Marfatia YS. Clinical study of cutaneous drug eruptions in 200 patients. Indian J Dermatol Venereol Leprol 2008. 74:80.	
4811	2008	Gresik CM. Brewster LP. Abood G. Supple KG. Silver GM. Gamelli RL. Nickoloff BJ. Ecthyma Gangrenosum Following Toxic Epidermal Necrolysis Syndrome in a 3 year old boy – a Survivable Series of Events. J Burn Care Res 2008. 29(3):555-555.	
4812	2008	Sharma VK. Sethuraman G. Minz A. Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and SJS-TEN overlap: a retrospective study of causative drugs and clinical outcome. Indian J Dermatol Venereol Leprol 74:238-240. 2008	
4813	2008	Yun SJ. Choi M-S. Piao MS. Lee J-B. Kim S-J. Won YH. Lee S-C. Serum Lactate Dehydrogenase is a Novel Marker for the Evaluation of Disease Severity in the Early Stage of Toxic Epidermal Necrolysis. Dermatology 2008; 217:254-259	
4814	2009	Levi N. Bastuji-Garin S. Mockenhaupt M. Roujeau JC. Flahault A. Kelly JP. Martin E. Kaufman DW. Maisson P. Medications as risk factors of Stevens-Johnson syndrome and toxic epidermal necrolysis in children: a pooled analysis. Pediatrics 2009 Feb. 123(2):e297-304. Epub 2009 Jan 19	
4815	2009	Levi N. Bastuji-Garin S. Mockenhaupt M. Roujeau JC. Flahault A. Kelly JP. Martin E. Kaufman DW. Maisson P. Medications as Risk Factors of Stevens-Johnson syndrome and Toxic Epidermal Necrolysis in Children: A Pooled Analysis. Pediatrics 2009; 123:e297-e304.	

Exh No.	Date	Description	Defendants' Objections
4816	2009	Yang Y. Xu J. Li F. Zhu X. Combination therapy of intravenous immunoglobulin and corticosteroid in the treatment of toxic epidermal necrolysis and Stevens-Johnson syndrome: a retrospective comparative study in China. Internatl J Dermatol. 2009; 48: 1122-1128.	
4817	2009	Rijal A. Agrawal S. Outcome of Stevens Johnson syndrome and toxic epidermal necrolysis treated with corticosteroids. Indian J Dermatol Venereol Leprol 2009; 75: 613- 614.	
4818	2010	Shiga S. Cartotto RJ. What are the fluid requirements in toxic epidermal necrolysis? Burn Care Res 2010 Jan-Feb. 31(1):100-4	
4819	No date	Fritsch PO. Ruiz-Maldonado R. Stevens-Johnson Syndrome—Toxic Epidermal Necrolysis. In Freedberg IM. Eisen AZ. Wolff K. Austen KF. Goldsmith LA. Katz SI. Fitzpatrick TB (eds) Fitzpatrick's Dermatology in General Medicine. New York. McGraw-Hill. pp. 644-654.	
4820	No date	Fritsch PO. Ruiz-Maldonado R. Stevens-Johnson Syndrome—Toxic Epidermal Necrolysis. In Freedberg IM. Eisen AZ. Wolff K. Austen KF. Goldsmith LA. Katz SI. Fitzpatrick TB (eds) Fitzpatrick's Dermatology in General Medicine. New York. McGraw-Hill. pp. 644-654.	
4821	12/6/2010	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Randall Tackett, Ph. D.	
4822	12/6/2010	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Dr. Scheffer Tseng	
4822.1	2011	Expert Report, Curriculum Vitae, and all Supporting Documents and Exhibits of Dr. Scheffer Tseng as produced and relied on in Maya, et ux. v. J&J, et al.	
4822.1	2011	Supplement to Expert Report served 4.25.11	
4823	12/6/2010	Expert Report of Dr. Sheffer Tseng Exhibit A - Curriculum Vitae	
4824	No date	Expert Report of Dr. Sheffer Tseng Exhibit B - What Causes TEN? Index	

Exh No.	Date	Description	Defendants' Objections
4825	No date	Expert Report of Dr. Sheffer Tseng Exhibit C - SCIENTIFIC LITERATURE ON THE RELATIONSHIP OF IBUPROFEN TO SJS AND TEN INDEX	
4826	2008	Expert Report of Dr. Sheffer Tseng Exhibit D - FDA Drug Safety Newsletter Winter 2008	
4827	2006	Expert Report of Dr. Sheffer Tseng Exhibit E - Motrin Label and Medication Guide Dated January 2006	
4828	2000	Expert Report of Dr. Sheffer Tseng Exhibit F - Box labeling for Children's Motrin Oral Suspension, Berry Flavored 2000	
4829	2001	Expert Report of Dr. Sheffer Tseng Exhibit G - Box labeling for Children's Motrin Oral Suspension, Grape Flavored 2001	
4830	No date	Expert Report of Dr. Sheffer Tseng Exhibit H - Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	
4831	1972	Kauppinen, K. Cutaneous Reactions to Drugs, A Clinical Study, Acta Dermato-Venereologica, 1972 V. 52, Sup. 68	
4832	1978	Sternlieb, P., et al., NY State J Med, "Stevens-Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen," pp.1239-1243, 1239(July 1978).	
4833	1984	Wintroub, B. U., et al., Current Perspectives in Immunodermatology, "Cutaneous Reactions to Drugs," pp.75-97, 85 (MacKie, R. M. (ed) Churchillill Livingstone 1984).	
4834	1989	Stern, R. S., et al., Pharmcol Skin, "Adverse Cutaneous reactions to Nonsteroidal Anti-Inflammatory Drugs," pp. 148-156, 150 (Hensby, C., et al. (eds.) Basel Karger 1989).	
4835	1989	Stern, R. S., et al., J Am Acad Dermatol, "Usefulness of Case report Literature in Determining Drugs Repsonsible for Toxic Epidermal Necrolysis," 21(2) 317-322, 320 (1989).	
4836	1989	Bigby, Stern, R. S., et al., Primay Care, "Allergic Cutaneous Reactions to Drugs," 16(3) 713-727, 714 (1989).	

Exh No.	Date	Description	Defendants' Objections
4837	1990	Roujeau, et al., J. of the Amer. Acad. of Dermatology, "Continuing medical education, Toxic Epidermal Necrolysis [Lyell Syndrome]", Vol. 23, No. 6, Part 1; 1039-1058 [1990].	
4838	1995	Sharma, V. K., et al., Ped Derm, "Clinical Pattern of Cutaneous Drug Eruption Among Children and Adolescents in North India," 12(2) 178-183, 180 (1995).	
4839	1996	Khoo, A. K. M., et al., Burns, "Toxic Epidermal Necrolysis in a Burns Centre: A 6-Year Review," 22(4) 275-278, 276 (1996).	
4840	1996	McWhinney CD, Dudley MW, Bowlin TL, Peet NP, Schook L, Bradshaw M, De M, Borcharding DR, Edwards CK 3rd: Activation of adenosine A3 receptors on macrophages inhibits tumor necrosis factoralpha. <i>Eur J Pharmacol</i> 1996, 310:209-216. 20	
4841	1998	Becker C, Barbulescu K, Hildner K, Meyer zum Buschenfelde KH, Neurath MF: Activation and methotrexate-mediated suppression of the TNF alpha promoter in T cells and macrophages. <i>Ann N Y Acad Sci</i> 1998 859:311-314	
4842	1999	Fritsch, P.O., et al., Fitzpatrick's Dermatology in General Medicine, "Stevens-Johnson Syndrome - Toxic Epidermal Necrolysis," pp.644-654, 647 (5th ed., Freedberg, I.M., et al. (eds.) McGraw-Hill 1999).	
4843	1999	Paul, C. N., et al., J Burn Care & Rehab, "Case Report: Oxaprozin and Fatal Toxic Epidermal Necrolysis," 19(4) 321-323, 321 (1999).	
4844	2000	Naisbitt, D. J., et al., Drug Safety, "Immunological Principles of Adverse Drug Reactions: The Initiation and Propagation of Immune Responses Elicited by Drug Treatment" 23(6) 483-507, 486 (2000).	
4845	2001	Majumdar S, Aggarwal BB: Methotrexate suppresses Nfkapab activation through inhibition of IkappaBalpha phosphorylation and degradation. <i>J Immunol</i> 2001 167:2911-2920	

Exh No.	Date	Description	Defendants' Objections
4846	2002	Stern and Shear, Cutaneous Medicine & Surgery, 1996 Ch. 43:412-425 19 Chan E. Cronstein B. Molecular action of methotrexate in inflammatory diseases. Arthritis Research, 2002 4:266-273	
4847	2003	Mockenahupt, M., et al., J Rheum, "The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Antiinflammatory Drugs: A Multinational Perspective," 30(10) 2234-2240, 2236 (Table 1) (2003).	
4848	2004	Taghian, M., et al., J Peds, "Acute Vanishing Bile Duct Syndrome After Ibuprofen Therapy in a Child," 273-276, 275 (Table) (Aug. 2004).	
4849	2005	Paquet, P., et al., J Oral Pathol Med, "Cystic Lesion of the Parotid Following Drug-Induced Toxic Epidermal Necrolysis" 34: 380-2 (2005).	
4850	2005	Di Pascuale MA, Espana EM, Liu D T-S, Kawakita T, Li W, Gao YY, Baradaran-Rafii A, Raju VK, Tseng SCG. Correlation of corneal complications with eyelid cicatricial pathologies in Tiffanys with Steven Johnson syndrome and toxic epidermal necrolysis syndrome. Ophthalmology 112:904-912, 2005.	
4851	2005	Tseng SCG, Di Pascuale MA, Liu DT-Z, Gao Y-Y, Baradaran-Rafii, A. Intraoperative mitomycin C and amniotic membrane transplantation for fornix reconstruction in severe cicatricial ocular surface diseases. Ophthalmology 112:896-903, 2005.	
4852	2007	Yamane, Y., et al. Allergology Int'l, "Analysis of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Japan from 2000 to 2006," 56 (4) 1-7, 3 (2007).	
4853	2007	Raksha, M. P., et al., Indian J Dermatol Venereol Leprol, "Clinical Study of Cutaneous Drug Eruption in 200 Patients," 74(80) 80-84, 81 (2007).	
4854	2007	Yawalkar, N., Drug Hypersensitivity, "Maculopapular Drug Eruptions," pp. 242-250, 246 (Pichler, W.J. (ed.) Basel, Karger 2007).	

Exh No.	Date	Description	Defendants' Objections
4855	2009	Tseng SCG. Acute management of Stevens-Johnson syndrome and toxic epidermal necrolysis to minimize ocular sequelae. <i>Editorial</i> . Am J Ophthalmol 147[6]:949-51; 2009.	
4856	2009	Shay E, Kheirkhah A, Liang L, Sheha H, Gregory DG, Tseng SCG. Amniotic membrane transplantation as a new therapy for acute Stevens-Johnson syndrome. Surv Ophthalmol, 54[6]:686-96, 2009.	
4857	2010	Shay E, Khadem JJ, Tseng SCG. Efficacy and limitation of sutureless amniotic membrane transplantation for acute toxic epidermal necrolysis. Cornea 29[3]:359-61, 2010.	
4858	2010	Fu Y, Gregory DG, Sippel KC, Bouchard CS, Tseng SCG. The ophthalmologist's role in the management of acute Stevens - Johnson Syndrome and toxic epidermal Necrolysis. Ocular Surface, in press, 2010.	
		Safety and Adverse Event Reporting	
5000	1997	Pharmacia & Upjohn (PNU) spontaneous reports of SJS & TEN transferred to McNeil in June 1997 Index of FDA 1639s 7/01/1991 thru 7/20/1992	Lacks authentication (Rule 901)
5001	2003	The FDA spontaneous reports printouts (SRS and AERS) from 1969 - 2003 for single ingredient ibuprofen products;	Lacks authentication (Rule 901)
5002	2007	Spontaneous Reports of SJS TEN, Lyell Syndrome related to Motrin / Ibuprofen 11/4/1997 thru 6/16/2007	Lacks authentication (Rule 901)
5003	No date	The CSM ADEs	Lacks authentication (Rule 901)
5004	No date	MCA adverse event reports	Lacks authentication (Rule 901)
5005	No date	Comprehensive Review of the Safety of Ibuprofen in Pediatric Patients;	
5006	No date	FDC reports on Motrin and ibuprofen products;	Lacks authentication (Rule 901)
5007	No date	WHO ADE's for Ibuprofen	Lacks authentication (Rule 901)
		Depositions	
		McNeil Corporate Representative Depositions	

Exh No.	Date	Description	Defendants' Objections
5500	5/19/2004	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 5/19/04	
5501		Exhibit No. 1 Notice of Deposition	
5502		Exhibit No. 2 Curriculum Vitae	
5503		Exhibit No. 3 List of Previous Depositions/Trials	
5504		Exhibit No. 4 Ibuprofen Review Document	Lacks authentication (Rule 901)
5505		Exhibit No. 5 Response Document from McNeil regarding Labeling Changes	
5506		Exhibit No. 6 Printout from DrugLogic Web Site	Lacks authentication (Rule 901)
5507	10/27/2003	Exhibit No. 7 Response Document to Approval Letter, 10/27/03	
5508	9/14/1983	Exhibit No. 8 Memorandum to T.N. Gates from C.E. Hammes, 9/14/83	
5509	8/9/1983	Exhibit No. 9 Memorandum to Advisory Committee Members, 8/09/83	
5510		Exhibit No. 10 Report by Lewis Goldfrank on Ibuprofen Toxicity	Lacks authentication (Rule 901)
5511	6/18/1984	Exhibit No. 11 Petition for Reconsideration, 6/18/84	
5512	5/31/1984	Exhibit No. 12 Summary Basis of Approval Letter, 5/31/84	
5513		Exhibit No. 13 Printout of McNeil Web Site	Lacks authentication (Rule 901)
5514	6/10/97	Exhibit No. 14 Internet Printout of Article from Pittsburgh Post Gazette, 6/10/97	
5515	6/3/1994	Exhibit No. 15 Results of Boston University Fever Study, 6/3/94	
5516	11/1/1993	Exhibit No. 16 Letter from Allen Mitchell, 11/1/93 regarding Draft Copy of Final Report	
5517	3/31/1988	Exhibit No. 17 Letter from Thomas N. Gates, 3/31/88	
5518		Exhibit No. 18 Chart Based on FDA Data	Lacks authentication (Rule 901)
5519	5/20/2004	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 5/20/04	
5520		Exhibit No. 19 Amended Notice of Deposition	
5521	1969	Exhibit No. 20 First Report on Ibuprofen, March 1969	
5522	10/27/1987	Exhibit No. 21 Letter from J.B. Nick; re: Statistical Report for Protocol; 10/27/87	

Exh No.	Date	Description	Defendants' Objections
5523		Exhibit No. 22 Letter from B. A. Byerly; re: Statistical	Lacks authentication (Rule 901)
5524	10/27/1987	Report for Protocol; 10/27/87	
5525	1/29/1990	Exhibit No. 23 Letter from Paula J. Oliver, re: Industry Meeting; 1/29/90	
5526		Exhibit No. 24 Statistical Review and Evaluation	Lacks authentication (Rule 901)
5527		Exhibit No. 25 Table 13 Comparison Report	Lacks authentication (Rule 901)
5528		Exhibit No. 26 Boston University Fever Study, Table 2	
5529		Exhibit No. 27 Excerpt from OTC Children's Motrin Suspension Report	
5530		Exhibit No. 28 Label excerpt on Motrin	
5531		Exhibit No. 29 Invoice Register by Vendor	Lacks authentication (Rule 901)
5532	7/25/07	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 7/25/07	
5533		Exhibit 1 List of depositions	
5534		Exhibit 2 Curriculum vitae	
5535	3/26/1993	Exhibit 3 Letter dated 03/26/93, 2pp.	
5536		Exhibit 4 Attachment I	
5537	5/31/84	Exhibit 5 Letter dated 5/31/84	
5538	12/19/1984	Exhibit 6 Letter submitted to FDA 12/19/84	
5539		Exhibit 7 Memo dated 11/2/94	
5540	11/2/1994	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 10/26/07	
5541		Exhibit 8: Copy of Children's Motrin Box and Bottle	
5542	1/29/1990	Exhibit 9: 2-pg. Memo, 1/29/90 to Distribution from Paula J. Oliver	
5543	1/29/1990	Exhibit 10: Letter, 5/3/90 to John G. Harter, MD from Anthony R. Temple, MD	
5544	10/9/1990	Exhibit 11: 2-pg. Memo, 10/9/90 to Distribution from Paula J. Oliver	
5545	12/20/90	Exhibit 12: Protocol, An Assessment of the Safety of Pediatric Ibuprofen Sponsored by McNeil Consumer Products Company, 12/20/90	
5546	3/3/1995	Exhibit 13: Fax, 3/3/95 to Willie Pagsuyuin from Susan Guckenheimer	
5547		Exhibit 14: Patient Data Listing for Study 90-056	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
5548		Exhibit 15: Patient Data Listing for Study 90-056	Lacks authentication (Rule 901)
5549	11/13/2007	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 11/13/07	
5550	2001	Exhibit 1 Children's Motrin Label copyright 2001	
5551		Exhibit 2 Ibuprofen Review prepared for David E. Collins	
5552		Exhibit 3 Memo dated August 17th, 1983 with an attached table	
5553	9/19/1983	Exhibit 4 Memo submitted by McNeil to the Arthritis Advisory Committee on September 19th, 1983	
5554		Exhibit 5 Trade and Government Memos	
5555		Exhibit 6 Memo from J.R. Chiesa to all employees, Subject: Legal action	
5556	5/31/1984	Exhibit 7 Letter dated May 31st, 1984	
5557		Exhibit 8 Letter	
5558		Exhibit 9 Petition for reconsideration	
5559		Exhibit 10 Letter from Lewis Goldfrank	
5560		Exhibit 11 Decision from the U.S. District court	
5561	7/28/1983	Exhibit 12 Memo to T.N. Gates dated July 28th, 1983	
5562		Exhibit 13 Memo from Kim McKonly to Laura Reel dated July 19th, 1999, Subject: Adverse event listing requested	
5563	Jul-78	Exhibit 14 Article published July of 1978	
5564	3/31/1998	Exhibit 15 McNeil's NDA dated March 31, 1988	
5565	12/4/2007	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 12/4/07	
5566	2001	Exhibit 1 Children's Motrin Label copyright 2001	
5567		Exhibit 2 Ibuprofen Review prepared for David E. Collins	
5568	8/17/1983	Exhibit 3 Memo dated August 17th, 1983 with an attached table	
5569	9/17/1983	Exhibit 4 Memo submitted by McNeil to the Arthritis Advisory Committee on September 19th, 1983	
5570		Exhibit 5 Trade and Government Memos	
5571		Exhibit 6 Memo from J.R. Chiesa to all employees, Subject: Legal action	

Exh No.	Date	Description	Defendants' Objections
5572	5/31/1984	Exhibit 7 Letter dated May 31st, 1984	
5573		Exhibit 8 Letter	
5574		Exhibit 9 Petition for reconsideration	
5575		Exhibit 10 Letter from Lewis Goldfrank	
5576		Exhibit 11 Decision from the U.S. District court	
5577	7/28/1983	Exhibit 12 Memo to T.N. Gates dated July 28th, 1983	
5578	7/19/1999	Exhibit 13 Memo from Kim McKonly to Laura Reel dated July 19th, 1999, Subject: Adverse event listing requested	
5579	Jul-78	Exhibit 14 Article published July of 1978	
5580	3/31/1988	Exhibit 15 McNeil's NDA dated March 31, 1988	
5581	12/5/2007	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 12/5/07	
5582		Exhibit 1, Curriculum vitae	
5583		Exhibit 2, JAMA - An Assessment of the Safety of Pediatric Ibuprofen – A Practitioner-Based Randomized Clinical Trial -MC12A 001953 through MC12A 001958	
5584		Exhibit 3, Patient Data Listing for Study 90-056 - Children's Motrin Ibuprofen Suspension	
5585		Exhibit 4, Ibuprofen Review - MC068369 through MC068407	
5586		Exhibit 5, Ibuprofen: An analysis of Safety and Efficacy - MC065017 through MC065040	
5587		Exhibit 6, Ibuprofen toxicity. A 134 review of adverse reactions and overdose -LFR00332422 through LFR00332443	
5588		Exhibit 7, A comparison of acetaminophen and ibuprofen side effects - MC068408 through MC068427,	
5589		Exhibit 8, Amended notice of deposition and demand for production of documents	
5590		Exhibit 9, Petition for reconsideration - LFR00199255 through LFR00199264	
5591	12/11/2007	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 12/11/07	
5592	5/4/1992	Exhibit 16 - Memorandum dated 5/4/92 to A.R. Temple, M.D., from B.H. Korberly, PharmD (Bates No. MC070764)	
5593		Exhibit 17 - Article titled "An Assessment of the Safety of Pediatric Ibuprofen" (5 pages)	

Exh No.	Date	Description	Defendants' Objections
5594		Exhibit 18 Document titled "Patient Data Listing for Study 90-056, Children's Motrin Ibuprofen Suspension" (Bates No. MOT00000761) ("Confidential Pursuant to Protective Order")	
5595	3/28/1995	Exhibit 19 - Memorandum dated 3/28/95 to McNeil CPC Employees from B.D. Perkins (Bates No. MC063520)	
5596		Exhibit 20 Compilation of MedWatch forms (29 pages) ("Confidential Pursuant to Protective Order")	Lacks authentication (Rule 901)
5597		Exhibit 21 - Article titled "Medication Use and the Risk of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis" (Bates Nos. 00268 to 00275)	
5598		Exhibit 22 - Article titled "The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Antiinflammatory Drugs: A Multi-national Perspective" (8 pages)	
5599	3/21/2003	Exhibit 23 String of e-mails, the latest of which is dated 3/21/03 to Anthony Temple from Kenneth Kwong (Bates No. MOT00007455.1 and MOT00007455.2) ("Confidential Pursuant to Protective Order")	
5600	3/26/2003	Exhibit 24 String of e-mails, the latest of which is dated 3/26/03 to Hiral Mankad from Anthony Temple (Bates Nos. MOT00007454 and MOT00007455) ("Confidential Pursuant to Protective Order")	
5601	4/21/2003	Exhibit 25 String of e-mails, the latest of which is dated 4/21/03 to Helen Hohman from Anthony Temple (Bates Nos. MOT00007436 to MOT00007439) ("Confidential Pursuant to Protective Order")	
5602	10/1/2003	Exhibit 26 String of e-mails, the latest of which is dated 10/1/03 to Kenneth Kwong and Anthony Temple from Danalynn Volpe (Bates Nos. MOT00007409 to MOT00007412)	
5603	6/30/2004	Exhibit 27 String of e-mails, the latest of which is dated 6/30/04 to Thomas Pulliam from Anthony Temple (Bates Nos. MOT00007336 and MOT0000737)	

Exh No.	Date	Description	Defendants' Objections
5604	2/11/2005	Exhibit 28 String of e-mails, the latest of which is dated 2/11/05 to Kathy Fallon and Anthony Temple from Jeffrey Leebaw (Bates Nos. MOT00007327.1 to MOT00007439) ("Confidential Pursuant to Protective Order")	
5605		Exhibit 29 Collection of e-mails from Lois Clymer to Minnie Baylor-Henry, et al., with attachments (10 pages) ("Confidential Pursuant to Protective Order")	
5606	2/20/2008	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 2/20/08	
5607		Exhibit 30 Notice, Bates MOT00007205-7229	
5608		Exhibit 31 Inlingua document, no Bates numbers, 16 pages	Lacks authentication (Rule 901)
5609		Exhibit 32 Patient Information Leaflet, no Bates numbers, 2 pages	Lacks authentication (Rule 901)
5610		Exhibit 33 Cover letter with enclosure, no Bates numbers, 5 pages	Lacks authentication (Rule 901)
5611		Exhibit 34 Fax transmittal with attachments, Bates MC071324-71327	
5612		Exhibit 35 Previously marked Exhibit Nelson-6, Bates MC044005-44008	
5613		Exhibit 36 Letter from DHHS no Bates numbers, 14 pages	Lacks authentication (Rule 901)
5614		Exhibit 37 Medical Officer Review, Bates MC063457-63485	
5615		Exhibit 38 Presentation, Bates MCPC/CM95-1-CM95-3	Lacks authentication (Rule 901)
5616		Exhibit 39 McNeil Consumer Products Company Clinical Study Report, Bates MC 074066-074140	
5617		Exhibit 40 Supplemental Labeling Request - CBE, no Bates, 8 pages	
5618		Exhibit 41 McNeil's Response to FDA's Proposed Labeling for OTC Non-Steroidal Anti-Inflammatory Drug (INSAID) Products, Bates MOT 00033242-33261	
5619	5/20/2008	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 5/20/08	
5620		Exhibit 1 Plaintiffs' Notice of Intent to Take Videotaped Oral Deposition of Anthony Temple, M.D., with Subpoena Duces Tecum	
5621		Exhibit 2 Curriculum Vitae	

Exh No.	Date	Description	Defendants' Objections
5622	11/13/2007	Exhibit 3 11-13-07 Deposition of Anthony R. Temple, M.D.	
5623	9-14-83	Exhibit 4 9-14-83 McNeil Memo to T. N. Gates from C. E. Hammes, Copied to A. R. Temple	
5624	5-31-84	Exhibit 5 5-31-84 Letter to Robert Temple, 15 M.D., from Craig E. Hammes, with Attachments	
5625	6/19/1984	Exhibit 6 6-19-84 McNeil Memo to T. N. Gates from C. E. Hammes, Copied to A. R. Temple, M.D.	
5626	6-18-84	Exhibit 7 6-18-84 Petition For Reconsideration Produced Document Entitled March '69 (First Report) April '86	
5627	3/31/1988	Exhibit 9 3-31-88 McNeil New Drug Application	
5628	1/29/1990	Exhibit 10 1-29-90 Minutes of Industry Meeting	
5629		Exhibit 11 Ibuprofen Marketing Chronology	Lacks authentication (Rule 901)
5630	12/22/1993	Exhibit 12 McNeil Consumer Products Company Clinical Study Report, Boston University Fever Study, 12-22-93 Final Report	
5631		Exhibit 13 Boston University Fever Study, Table 2	
5632	6/3/1994	Exhibit 14 6-3-94 Letter to Barbara Korberly from Allen A. Mitchell and Samuel Lesko Enclosing Draft Manuscripts of the Boston University Fever Study	
5633	11-1-93	Exhibit 15 11-1-93 Letter to Anthony Temple, M.D., from Allen Mitchell with Attached Boston University Fever Study Draft Final Report	
5634		Exhibit 16 Medical Officer Review for Children's Motrin Ibuprofen Suspension	
5635	3/28/1995	Exhibit 17 3-28-95 Memo to McNeil CPC Employees from B. D. Perkins	
5636	6/24/2008	Trial Testimony from Johnson v. Johnson & Johnson of Anthony Temple, M.D., 6/24/08	
5637	6/26/2008	Trial Testimony from Johnson v. Johnson & Johnson of Anthony Temple, M.D., 6/26/08	
5638	6/27/2008	Trial Testimony from Johnson v. Johnson & Johnson of Anthony Temple, M.D., 6/27/08	
5639	6/30/2008	Trial Testimony from Johnson v. Johnson & Johnson of Anthony Temple, M.D., 6/30/08	

Exh No.	Date	Description	Defendants' Objections
5640	10/2/2008	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 10/2/08	
5641		Exhibit 1 Plaintiffs' Notice of Videotaped Deposition	
5642		Exhibit 2 Curriculum Vitae	
5643		Exhibit 3 Ibuprofen Marketing Chronology	Lacks authentication (Rule 901)
5644		Exhibit 4 Ibuprofen Review	
5645		Exhibit 5 Arthritis Advisory Committee Meeting Handouts	
5646		Exhibit 6 Ibuprofen: An analysis of safety and efficacy	
5647		Exhibit 7 Pediatric MOTRIN (ibuprofen) products	
5648		Exhibit 8 Draft copy of Final Report	
5649		Exhibit 9 McNeil Consumer Products Company Clinical...	
5650	3-Jun-94	Exhibit 10 June 3, 1994 letter to Barbara Korberly	
5651		Exhibit 11 Adverse Experience Monitoring Process	Lacks authentication (Rule 901)
5652		Exhibit 12 Adverse Experience Monitoring Process	Lacks authentication (Rule 901)
5653		Exhibit 13 Procedure for MCSP Safety Review Board...	
5654		Exhibit 14 Photocopies of Children's Motrin labeling	
5655	5/31/1984	Exhibit 15 5/31/84 letter to Mr. Temple with attachment	
5656		Exhibit 16 Petition for Reconsideration	
5657	11/12/2008	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 11/12/08	
5658		Exhibit 1 Curriculum Vitae	
5659		Exhibit 2 Letter from the Department of Human Services to Roger E. Salisbury, M.D.	
5660		Exhibit 3 Children's Motrin Label	
5661	9-Oct-90	Exhibit 4 October 9, 1990 memo from Paula J. Oliver to Distribution	
5662		Exhibit 5 Ibuprofen Review	
5663		Exhibit 6 Petition for Reconsideration.	
5664	19-Jun-84	Exhibit 7 June 19, 1984 memo from C.E. Hammes to T.N. Gates	

Exh No.	Date	Description	Defendants' Objections
5665	3/25/2009	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 3/25/09	
5666	10/13/2009	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 10/13/09	
5667		Exhibit 1 The New England Journal of Medicine article, Medication Use and the Risk of Stevens- Johnson Syndrome or Toxic Epidermal Necrolysis	
5668		Exhibit 2 Children's Motrin Cold article from Motrin.com	
5669	7/22/1996	Exhibit 3 MedWatch report dated 7/22/1996	
5670	24-Aug-06	Exhibit 4 August 24, 2006 letter from Cincinnati Children's Hospital	
5671		Exhibit 5 Article from The American Gastroenterology Association	
5672	1991	Exhibit 6 1991 Physicians' Desk Reference information for ibuprofen	
5673	1993	Exhibit 7 1993 Physicians' Desk Reference information for ibuprofen	
5674	1994	Exhibit 8 1994 Physicians' Desk Reference information for ibuprofen	
5675	1995	Exhibit 9 1995 Physicians' Desk Reference information for ibuprofen	
5676	1996	Exhibit 10 1996 Physicians' Desk Reference information for ibuprofen	
5677	3/31/1995	Exhibit 11 MedWatch report dated 3/31/95	
5678	5/15/95	Exhibit 12 MedWatch report dated 5/15/95	
5679	2/1/1995	Exhibit 13 MedWatch report dated 2/1/95	
5680	11/10/1997	Exhibit 14 MedWatch report dated 11/10/97	
5681	5/28/1996	Exhibit 15 MedWatch report dated 5/28/96	
5682		Exhibit 16 Former deposition testimony of Dr. Temple	
5683		Exhibit 17 Copy of Children's Motrin box	
5684	5/12/2010	Oral deposition and accompanying exhibits of Anthony Temple, M.D., 5/12/2010	
5685		Exhibit 1 Notice of taking audio-visual deposition of Dr. Anthony Temple	
5686		Exhibit 2 Notice of taking 30(b)(6) audio-visual deposition of McNeil-PPC, Inc. D/B/A McNeil Consumer & Specialty Pharmaceuticals and D/B/A McNeil Consumer Healthcare, a division of McNeil, PPC, Inc.	

Exh No.	Date	Description	Defendants' Objections
5687		Exhibit 3 Article from The New England Journal of Medicine, "Medication Use and the Risk of Stevens-Johnson Syndrome of Toxic Epidermal Necrolysis"	
5688		Exhibit 4 Ibuprofen Review Prepared for David E Collins	
5689		Exhibit 5 Trade & Govt. Memos	
5690	5/31/84	Exhibit 6 Letter from Craig Hammes to Dr. Temple; 5/31/84	
5691	5/25/1984	Exhibit 7 Letter from J.R. Chiesa to All Employees Subject - Legal Action; 5/25/84	
5692		Exhibit 8 Letter from Thomas Gates, M.D. to Health	
5693	6/18/1984	Exhibit 9 Petition for Reconsideration; 6/18/84	
5694	7/28/1983	Exhibit 10 Letter from T.N. Gates, M.D., S. Levi, Ph.D. to J.R. Chiesa, D.E. Collins re Rx to OTC Switch of ibuprofen (Motrin); 7/28/83	
5695		Exhibit 11 A letter from McNeil to the FDA regarding a new drug application for Ibuprofen Pediatric Suspension, 80mg/5ml.	
5696		Exhibit 12 Pages out of Dr. Temple's Day Planner	
5697		Exhibit 13 McNeil Consumer Products Company Clinical Study Report, Protocol 90-056, Phase IV, "An Assessment of the Safety of Pediatric Ibuprofen, Boston University Fever Study"	
5698	3/28/1995	Exhibit 14 Letter from B.D. Perkins to McNeil CPC Employees; 3/28/95	
5699	2002	Exhibit 15 2002 Label Set	
5700	2003	Exhibit 16 2003 Label Set	
5701	6/22/2006	Exhibit 17 Letter to Dr. Salisbury from the Department of Health & Human Services; 6/22/06	
5702		Exhibit 18 MedWatch reports	Lacks authentication (Rule 901)
5703		Exhibit 19 MedWatch report relating to the Samantha Reckis case	
5704		Exhibit 20 Suspect Adverse Reaction Report in the Reckis case	
5705		Exhibit 21 Draft MedWatch report relating to the Zachary Duffy case	

Exh No.	Date	Description	Defendants' Objections
5706		Exhibit 22 Suspect Adverse Reaction Report in the Duffy case	
5707	5/19/2004	Oral deposition and accompanying exhibits of Brenda Bass, 5/19/04	
5708		Exhibit 1 Notice Of Videotape Deposition and Subpoena Duces Tecum	
5709		Exhibit 2 Resume of Brenda Bass	
5710		Exhibit 3 Document headed "Consumer Market Overview"	
5711	11/21/2007	Oral deposition and accompanying exhibits of Carrie Corboy, 11/21/07	
5712		Exhibit 1 CV of Carrie E. Corboy, RPh, PharmD, 6 pages	
5713	19-Sep-03	Exhibit 2 Periodic Safety Update Report 19-Sep-2003, Bates LM006222-6357	
5714	20-May-03	Exhibit 3 26 Ibuprofen Addendum Periodic Safety Update Report 20 May 2003 - 31 December 2004, Bates LM006070-6221	
5715	5/13/2004	Oral deposition and accompanying exhibits of Edward Nelson, M.D., 5/13/04	
5716		Exhibit No. 1 Notice of Deposition	
5717		Exhibit No. 2 Curriculum Vitae	
5718		Exhibit No. 3 Dr. Nelson's Job Description	
5719		Exhibit No. 4 Organizational Chart	
5720	11/12/2002	Exhibit No. 5 11/12/2002 Letter from National Kidney Foundation to FDA	
5721		Exhibit No. 6 Listings of Adverse Reactions in Boston Fever Study	Lacks authentication (Rule 901)
5722	5/11/2004	Oral deposition and accompanying exhibits of Vivian Chester, 5/11/04	
5723		Exhibit No. 1 Notice of Deposition	
5724		Exhibit No. 2 Curriculum Vitae	
5725	2/26/1990	Exhibit No. 3 2/26/90 Pink Sheet	
5726		Exhibit No. 4 Letter forwarding Boston Fever Study Interim Report to Dr. Harter	
5727	6/9/1992	Exhibit No. 5 6/9/92 Letter from Lesko and Mitchell to Dr. Korberly	
5728		Exhibit No. 6 PediaProfen Suspension Annual Report no. 3	
5729	11/8/1994	Exhibit No. 7 11/8/94 Letter Proposing Revised Combined Package Insert	
5730	11/3/1994	Exhibit No. 8 McNeil CPC Record of Contact, 11/3/94	

Exh No.	Date	Description	Defendants' Objections
5731		Exhibit No. 9 List of New ADRs faxed to Willie Pagsuyu from Upjohn	
5732		Exhibit No. 10 Promotional Material Submitted to FDA	
5733	3/29/1993	Exhibit No. 11 3/29/93 Document from FDA Criticizing Brochure	
5734		Exhibit No. 12 McNeil Promotional Material	
5735		Exhibit No. 13 Indications for Prescription PediaProfen	
5736	1/20/1993	Exhibit No. 14 1/20/93 Letter from DDMAC, re: Promotional Material	
5737		Exhibit No. 15 Dear-Doctor Letter	
5738	5/20/1993	Exhibit No. 16 5/20/93 Letter from FDA	
5739		Exhibit No. 17 Transmittals of Advertisements and Promotional Labeling	
5740		Exhibit No. 18 Transmittals of Advertisements and Promotional Labeling	
5741		Exhibit No. 19 Transmittals of Advertisements and Promotional Labeling	
5742		Exhibit No. 21 Labeling Change	
5743		Exhibit No. 22 Final Printed Label	
5744		Exhibit No. 23 Aspirin-Sensitive Warning	
5745		Exhibit No. 24 Whitehall Robins Submission, Potential for Acetaminophen to Exhibit Cross-Reactivity in Individuals Allergic to Aspirin	
5746		Helzner Exhibit 1	
5747		Helzner Exhibit 11	
5748		Helzner Exhibit 10	
5749		Oliver Exhibit 10	
5750		Denisco Exhibit 9	
5751		Denisco Exhibit 14	
5752	8/9/2007	Oral deposition and accompanying exhibits of Vivian Chester, 8/9/07	
5753		Exhibit 1, MC06A 000035 through MC06A 000042	
5754		Exhibit 2, Zundel 000396	
5755		Exhibit 3, MC06A 000307	
5756		Exhibit 4, MC06A 000319	
5757		Exhibit 5, MC06A 000044 through MC06A 000045	
5758		Exhibit 6, Box and bottle label	
5759		Exhibit 7, MC06A 000068	

Exh No.	Date	Description	Defendants' Objections
5760	4/27/2004	Oral deposition and accompanying exhibits of Eileen Helzner 4/27/04	
5761	3/26/2004	Exhibit 1 5-page copy of document dated 3/26/04 entitled "Plaintiffs' First Amended Notice of Intent to Take Videotaped Oral Deposition of Dr. Eileen Helzner, with Subpoena Duces Tecum"	
5762		Exhibit 2 2-page entitled "Eileen Cohler Helzner, M.D."	
5763	2003	Exhibit 3 1-page copy of document dated 11/03 entitled "Management Board" MC000001	
5764		Exhibit 4 1-page copy of document entitled "Ibuprofen Pediatric Suspension 80mg/5ml, New Drug Application"	
5765		Exhibit 5 1-page copy of document entitled "Ibuprofen Pediatric Suspension 80mg=5ml, New Drug Application," MC06A 000841	
5766		Exhibit 6 1-page copy of document, MC067241	
5767		Exhibit 7 1-page copy of document entitled "3. Renal Effects," MC067243	
5768		Exhibit 8 1-page copy of document, MC067085	
5769		Exhibit 9 1-page copy of document, MC067068	
5770		Exhibit 10 1-page copy of document entitled "PediaProfen Suspension, NDA 19-842 S-001 (Drops)," plus attachments, MC08A 000959, MC08A 000970-MC08A 000974	
5771		Exhibit 11 1-page copy of document entitled "Children's MOTRIN Suspension 100mg/5mL, NDA 20-516/S-006, 'Final Printed Label,'" plus attachments, MC02A 000622-MC02A 000633	
5772	8/17/1983	Exhibit 12 1-page copy of memo dated 8/17/83 to Arthritis Advisory Committee from Judith K. Jones, M.D Ph.D., plus attachment MC067313-MC067314	
5773	1980-1982	Exhibit 13 1-page copy of document entitled "Michigan Medicaid-MMIS Data: 1980-82, Percent of NSAID-Exposed Patients With Selected Diagnoses Occurring Uniquely at Selected Times After Drug Exposure," MC067315	

Exh No.	Date	Description	Defendants' Objections
5774		Exhibit 14 1-page copy of document entitled "Summary of Safety and Efficacy Data From the New Drug Application Requesting that ADVIL (Ibuprofen) Be Approved for Non-Prescription Use" plus attachment MC067691, MC067738	
5775		Exhibit 15 1-page copy of document entitled "Figure 1 Adverse Drug Reactions to Ibuprofen Reported to CSM & FDA," MC067735	
5776		Exhibit 16 1-page copy of document, MC067728	
5777	Aug-84	Exhibit 17 1-page copy of document dated 8/84 entitled "Ibuprofen: An Analysis of Safety and Efficacy" plus attachment MC065017, MC065020	
5778	6/6/1984	Exhibit 18 1-page copy of letter dated 6/6/84 to Dear Health Writer from Thomas N. Gates, M.D., MC067171	
5779		Exhibit 19 1-page copy of document entitled "Ibuprofen Pediatric Suspension 80mg/5ml., New Drug Application," MC06A 000879	
5780	3/31/88	Exhibit 20 1-page copy of letter dated 3/31/88 to U.S. Food and Drug Administration from Thomas N. Gates, M.D. MC06A 000796	
5781		Exhibit 21 1-page copy of document entitled "Ibuprofen Pediatric Suspension 80mg/5ml, New Drug Application," MC06A 000844	
5782		Exhibit 22 1-page copy of document entitled "Single Dose Controlled Studies - Fever," MC08A 000606	
5783		Exhibit 23 1-page copy of document, MC08A 000607	
5784		Exhibit 24 1-page copy of memo dated 10/27/87 to Distribution from J. B. Nick, Ph.D. MC065874	
5785		Exhibit 25 1-page copy of document entitled "Ibuprofen Pediatric Suspension 80mg/5ml, New Drug Application," MC06A 000893	
5786		Exhibit 26 1-page copy of document 338 entitled "Table 30 Protocol 6-640," MC063303	
5787		Exhibit 27 1-page copy of document entitled "Ibuprofen Pediatric Suspension 80mg/5ml, New Drug Application," MC06A 000917	

Exh No.	Date	Description	Defendants' Objections
5788		Exhibit 28 1-page copy of document entitled "Page 4, NDA 19-842," MC013A 000286	
5789	5/11/2004	Oral deposition and accompanying exhibits of Tizianna Fox, 5/11/04	
5790		Exhibit No.1 Notice of Deposition	
5791		Exhibit No.2 Curriculum Vitae	
5792		Exhibit No.3 Documents from Dr. Temple's Files	
5793		Exhibit No.4 18 21 CFR 314.80	
5794		Exhibit No.5 Article "Medication Use and the Risk of Stevens-Johnson syndrome or Toxic Epidermal Necrolysis"	Lacks authentication (Rule 901)
5795		Exhibit No.6 Complaint Investigations	Lacks authentication (Rule 901)
5796		Exhibit No.7 Adverse Drug Experience Reporting	Lacks authentication (Rule 901)
5797		24 Exhibit No.8 case Reports	Lacks authentication (Rule 901)
5798	11/20/2007	Oral deposition and accompanying exhibits of Tizianna Fox, 11/20/07	
5799		Exhibit 1 Curriculum vitae of Tiziana M. Fox, PharmD, 5 pages	
5800		Exhibit 2 Adverse Drug Experience Reporting document, Bates MC000035-43 and attached blank page with exhibit sticker marked Fox Exhibit 8	Lacks authentication (Rule 901)
5801		Exhibit 3 MedWatch form Bates MC079449	Lacks authentication (Rule 901)
5802		Exhibit 4 Pharmacovigilance Adverse Event Routing Form, Bates LM001045	
5803		Exhibit 5 Product Information form, 1 page	
5804		Exhibit 6 Article pages 2234-2240 with attached document delivery form	
5805		Exhibit 7 MedWatch reports, Bates MOT00015628, LM000214-216, MC079629, MOT00015802-15804, MOT00015809-810, MOT00015805, MOT00015853-854, MOT00015863-867, MO079613 MC079621, MC079417, MC079676	Lacks authentication (Rule 901)
5806		Exhibit 8 Label Bates MC02A 000580	
5807	5/12/2004	Oral deposition and accompanying exhibits of Willie Pagsuyuin, 5/12/04	
5808		Exhibit No.1 Notice of Deposition	
5809		Exhibit No.2 Curriculum Vitae	

Exh No.	Date	Description	Defendants' Objections
5810	3/14/2009	Exhibit No.3 Memo to Dr. Temple from Paula Oliver, 3/14/89, re: Package Insert	
5811		Exhibit No.4 Fax from FDA to McNeil	
5812		Exhibit No.5 Letter Seeking to Combine ADE Reporting	
5813	4/1/1997	Exhibit No.6 Memo from Pagsuyu in to Others, 4/1/97, re: Pediatric Motrin Labeling	
5814		Exhibit No.7 Quarter ADE Reports	Lacks authentication (Rule 901)
5815		Exhibit No.8 Quarter ADE Reports	Lacks authentication (Rule 901)
5816		Chester Exhibit 7	
5817		Chester Exhibit 8	
5818		Chester Exhibit 9	
5819		Chester Exhibit 21	
5820		Helzner Exhibit 10	
5821		Helzner Exhibit 11	
5822		Oliver Exhibit 10	
5823		Oliver Exhibit 13 69	
5824		Denisco Exhibit 11	
5825	9/7/2007	Oral deposition and accompanying exhibits of Willie Pagsuyu in, 9/7/07	
5826		Exhibit 1, Curriculum vitae	
5827		Exhibit 2, Mc Neil CPC - record of contact - LFR01249939	
5828	4/4/1997	Exhibit 3, Letter dated April 4, 1997 to Robert O'Neill from Willie D. Pagsuyu in - MC06A 000342 through MC06A	
5829	6/11/1992	Exhibit 4, Letter dated June 11, 1992 to John G. Harter from Vivian Chester	
5830	6/27/1995	Exhibit 5, Fax transmittal dated June 27, 1995 to S. Raigrodski from Willie Pagsuyu in	
5831	6/15/1995	Exhibit 6, Letter dated June 15, 1995 to Robert F. Bedford from Vivian Chester - MC06A 000087 through MC06A 000088	
5832	5/10/1995	Exhibit 7, Letter dated May 10, 1995 to Robert F. Bedford from Vivian Chester - MC05A 001562 through MC05A 001574	
5833		Oral deposition and accompanying exhibits of Willie Pagsuyu in, 5/14/08	
5834		Exhibit 1 Curriculum Vitae 32	
5835	4/4/1997	Exhibit 2 Letter dated April 4, 1997, Bates stamped MC06A 000342 and MC06A000343	

Exh No.	Date	Description	Defendants' Objections
5836	6/1/1998	Exhibit 3 Letter dated June 1, 1998	
5837		Exhibit 4 Fax dated May 31, 1995, Bates stamped MC071324 through MC071327	
5838		Exhibit 5 Memo dated April 1, 1997, Bates stamped MC071608 and MC071639	
5839	1/21/2002	Exhibit 6 Children's Motrin Label, 1/21/02	
5840		Exhibit 7 Letter dated May 2009, 1995, Bates stamped MC063674 through MC063679	
5841	14-Jun-95	Exhibit 8 Memo dated June 14, 1995, Bates stamped MC063663 through MC063673	
5842	16-Jun-95	Exhibit 9 Letter dated June 16, 1995, Bates stamped MC063712 through MC063716	
5843		Exhibit 10 Dolormin for Children User Information	Lacks authentication (Rule 901)
5844		Exhibit 11 Department of Health Canada	Lacks authentication (Rule 901)
5845		Exhibit 12 Antalgit product information	Lacks authentication (Rule 901)
5846		Exhibit 13 Ipren product information	Lacks authentication (Rule 901)
5847	4/27/2004	Oral deposition and accompanying exhibits of Mary Joan Denisco, Pharm.D., 4/27/04	
5848		Exhibit 1 5-page copy of document dated 31226204 entitled "Plaintiffs' First Amended Notice of Intent to Take Videotaped Oral Deposition of Mary Joan Denisco, Pharm.D. Assistant Director for Medical Affairs"	
5849		Exhibit 2 3-page copy of document entitled "Curriculum Vitae"	
5850		Exhibit 3 1-page copy of document entitled "Boston University .Fever Study Enrollment/Consent Form" MC12A 001106	
5851		Exhibit 4 1-page copy of doatment entitled 'Meeting Minutes,' MC070890	
5852		Exhibit 5 1-page copy document entitled "Children's Motrin Ibuprofen Suspension, 100mg/5mL NDA 19-842, Supplemental New Drug Application MC074083 .	
5853		Exhibit 6 1-page copy of document entitled Follow-Up" plus attachment MCO70474, MC070467	

Exh No.	Date	Description	Defendants' Objections
5854	4/22/92	Exhibit 7 1-page copy of letter dated 4/22/92 to Anthony Temple, MD., from Allen A- Mitchell M.D., plus attachments MC07088 - MC070889 & MC070891-MC070892	
5855		Exhibit 8 1-page copy document Entitled "Boston Fever Study Frequency Distribution of Discharge Diagnosis (Cont'd), 1 st Interim Analysis" MC070886	
5856	2/13/1992	Exhibit 9 I page copy of letter dated 2/13/92 to Barbara Korberly, Pharm.D., from Allen A. Mitchell, M.D. and Samual M. Lesko, M.D., M.P.H., plus attachments, MC12A 001054-MC12A001058	
5857		Exhibit 10 1-page copy of document entitled "Pediatric ibuprofen, page 6" MC070695	
5858		Exhibit 12 1-page copy of document MC063479	
5859	12/31/1994	Exhibit 14 24 page copy of document entitled "SRS 11-93 through 12/31/94"	
5860	6/20/2007	Oral deposition and accompanying exhibits of Mary Joan Denisco, Pharm.D., 6/20/07	
5861		Exhibit 1 Curriculum Vitae (3 pgs.)	
5862	4/27/2004	Exhibit 2 Cover page of transcript dated 4/27/04 and pages 49 and 81	
5863		Exhibit 3 PDR excerpts (7 pgs.)	
5864		Exhibit 4 Memo dated November 8th, 1994 labeled FDA Contact Motrin Labeling (2 pgs.)	
5865		Exhibit 5 Memo dated 1/29/90 (2 pgs.)	
5866		Exhibit 6 Protocol - As Assessment of the Safety of Pediatric Ibuprofen	
5867		Exhibit 7 Article entitled Stevens-Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen	
5868		Exhibit 8 Children's Motrin package	
5869	11/21/2007	Oral deposition and accompanying exhibits of Mary Joan Denisco, Pharm.D., 11/21/07	
5870		Exhibit 1 CV of Mary Joan Denisco, PharmD, 3 pages	
5871		Exhibit 2 Letter November 7, 1990, Bates MC070463-464	
5872		Exhibit 3 Patient Data Listing for Study 90-056, Bates MOT00000761-760	
5873		Exhibit 4 Medical Office Review, Bates MC063457-485	

Exh No.	Date	Description	Defendants' Objections
5874		Exhibit 5 BUFS-Draft Final Report November 2, 1993, Bates MC070133-189 with blank purple page and page of JAMA previously marked Oliver Exhibit 8	
5875		Exhibit 6 Children's Motrin label, Bates MC02A 000580	
5876		Exhibit 7 Department of Health and Human Services, 25 pages	
5877		Exhibit 8 Email string, Bates MOT00004724	
5878		Oral deposition and accompanying exhibits of Paula Oliver, 4/28/04	
5879		Exhibit 1 5-page copy of document dated 3/31/04 entitled "Plaintiffs' Second Amended Notice of Intent to Take Videotaped Oral Deposition of Paula Oliver, Director of Regulatory Affairs"	
5880		Exhibit 2 2-page copy of document entitled "Paula J. Oliver"	
5881		Exhibit 3 3-page copy of document dated 2/10/98 entitled "McNeil Consumer Products Company, Exempt Position Description"	
5882		Exhibit 4 4-page copy of document dated 4/3/95 entitled "F-D-C Reports - 'The Tan Sheet'"	
5883		Exhibit 5 2-page copy of letter dated 9/15 from Debra L. Bowen, M.D.	
5884		Exhibit 6 9-page copy of letter dated 5/10/95 to Robert F. Bedford, M.D., from Vivian A. Chester, plus attachments	
5885		Exhibit 7 Multi-page copy of document entitled "New Product Bulletin"	
5886		Exhibit 8 Multi-page copy of document dated 3/22-29/95 entitled "An Assessment of the Safety of Pediatric Ibuprofen, A Practitioner-Based Randomized Clinical Trial"	
5887		Exhibit 9 Multi-page copy of document entitled "A Comprehensive Review of the Safety of Ibuprofen in Pediatric Patients"	
5888		Exhibit 10 1-page copy of document entitled "Trade & Govt.Memos," MC066971	

Exh No.	Date	Description	Defendants' Objections
5889		Exhibit 11 2-page copy of letter 123 dated 9/26/94 to Robert F. Bedford, M.D., from Vivian A. Chester, MC01A 001428-MC01A 001429	
5890		Exhibit 12 1-page copy of document dated 3/22/95 entitled "Motrin (ibuprofen) Suspension, 100mg/5mL NDA 20-516, Amendment #2 (Draft Labeling)," plus attachments, MC01A 001443-MC01A 001445	
5891		Exhibit 13 1-page copy of document dated 6/15/95 entitled "Children's Motrin Suspension, 100mg/5mL NDA 20-516, Amendment #3 (Package Insert)," plus attachments, MC01A 001465-MC01A 001472	
5892		Exhibit 14 4-page copy of letter 136 dated 6/1/98 to Debra L. Bowen, M.D., from Vivian A. Chester, MC06A 000734-MC06A 000737	
5893		Oral deposition and accompanying exhibits of Peter Bell, 4/28/04	
5894		Exhibit 1 4-page copy of document dated 3/31/04 entitled "Plaintiffs' Second Amended Notice of Intent to Take Videotaped Oral Deposition of Peter Bell with Subpoena Duces Tecum"	
5895		Exhibit 2 2-page copy of document entitled "Professional Experience"	
5896		Exhibit 3 1-page copy of document entitled "Top Marketing Executive"	
5897		Exhibit 4 1-page copy of document entitled "Ibuprofen Pediatric Suspension 80mg/5ml, New Drug Application," MC06A000829	
5898		Exhibit 5 1-page copy of memo dated 10/29/93 to W. A. Vernon from P. H. Bell, MC071501	
5899		Exhibit 6 2-page copy of letter dated 7/13/95 to Vivian Chester from Jean E. Raymond, P.A. MC071185-MC071186	
5900		Exhibit 7 5-page copy of document entitled "Answers to questions parents often ask about their child's fever and pain" MC071195-MC071199	
5901		Exhibit 8 1-page copy of letter to Dear Doctor from Anthony R. Temple, M.D., MC071200	

Exh No.	Date	Description	Defendants' Objections
5902		Exhibit 9 1-page copy of document dated 6/26/95 entitled "F-D-C Reports - 'The Tan Sheet,'" MC071203	
5903		Oral deposition and accompanying exhibits of Ashley McEvoy, 5/19/04	
5904		Exhibit 1 Notice of Videotape Deposition and Subpoena Duces Tecum	
5905		Exhibit 2 Resume of Ashley McEvoy	
5906		Exhibit 3 Children's Motrin Fact Sheet	
5907		Exhibit 4 Two-page document, Bates stamped MC072329 and MC072330	Lacks authentication (Rule 901)
5908		Exhibit 5 Two-page document, Bates stamped MC072271 and MC072272	Lacks authentication (Rule 901)
5909		Exhibit 6 Seven-page document, first with the heading "Ibuprofen Use in Pediatric Patients: Effective Counseling Methods"	Lacks authentication (Rule 901)
5910		Exhibit 7 Document headed "Boston University Safety Study Implications"	
5911		Exhibit 8 One-page document Bates stamped MC080379	Lacks authentication (Rule 901)
5912		Exhibit 9 One-page document Bates stamped MC080413	Lacks authentication (Rule 901)
5913		Exhibit 10 Document headed "POA Objectives and Strategies"	Lacks authentication (Rule 901)
5914		Oral deposition and accompanying exhibits of Ashley McEvoy, 4/1/09	
5915		Exhibit 1, CV	
5916		Exhibit 2, Label	
5917		Exhibit 3, PDR for over-the-counter Children's Motrin	
5918		Exhibit 4, McNeil document	Lacks authentication (Rule 901)
5919		Exhibit 5, Letter from the FDA to McNeil in April 2005	
5920		Exhibit 6, Study	
5921		Exhibit 7, "An Exploration of Dual Usage of Children's Tylenol and Children's Motrin" prepared by Strategic Frameworking, Inc., February 2001, for McNeil, Bates-stamped Numbers MOT 00059316 through '59349	
5922		Exhibit 8, document entitled "Children's Tylenol and Children's Motrin,"	

Exh No.	Date	Description	Defendants' Objections
5923		Exhibit 9, newsletter dated April 2001, Volume I, Issue 1	
5924		Exhibit 10, "Children's Tylenol/Children's Motrin Resistance Role Play Scenarios."	Lacks authentication (Rule 901)
5925		Exhibit 11, advertisements	
5926		Exhibit 12, Motrin advertisement	
5927		Exhibit 13, MOT 00007622	
5928		Exhibit 14, Ads	
5929		Exhibit 15, "Beat Advil Program."	
5930		Exhibit 16, informational material provided by McNeil to healthcare providers	
5931		Exhibit 17, Declaration	
5932		Oral deposition and accompanying exhibits of Bob Christiansen, 5/20/04	
5933		Exhibit 1 Notice Of Videotape Deposition and Subpoena Duces Tecum	
5934		Exhibit 2 Memo to Distribution from T.M. Fox, 9/24/93	
5935		Exhibit 3 Memo to Distribution from D.M. Hunt, 5/23/94	
5936		Exhibit 4 Memo to Distribution from D.M. Hunt, 7/19/94	
5937		Exhibit 5 Document headed "Adverse Drug Experience"	Lacks authentication (Rule 901)
5938		Exhibit 6 Document headed "Adverse Drug Experience Rates"	Lacks authentication (Rule 901)
5939		Exhibit 7 Memo to Distribution from Jeris P. Burnell, 3/3/97	
5940		Exhibit 8 Memo to Distribution from Jeris P. Burnell, 5/14/97	
5941		Exhibit 9 Memo to Distribution from Jeris P. Burnell, 8/13/97	
5942		Exhibit 10 Memo to Distribution from Lynn C. McIntire, 11/20/97	
5943		Exhibit 11 Memo to Distribution from Lynn C. McIntire, 5/14/98	
5944		Exhibit 12 Memo to Distribution from Lynn C. McIntire, 7/20/98	
5945		Exhibit 13 Memo to Distribution from Stacey A. Ross, 2/19/99	
5946		Exhibit 14 Memo to Distribution from Kelly Wright, 5/17/99	

Exh No.	Date	Description	Defendants' Objections
5947		Exhibit 15 Memo to Distribution from Erica C. Kobylinski, 11/3/99	
5948		Exhibit 16 Memo to Distribution from Erica C. Kobylinski, 2/16/00	
5949		Exhibit 17 One-page document Bates stamped MC078662	Lacks authentication (Rule 901)
5950		Exhibit 18 Document Bates stamped MC078801 through MC078809	Lacks authentication (Rule 901)
5951		Exhibit 19 Memo to Distribution from Erica C. Kobylinski, 1/24/01	
5952		Oral deposition and accompanying exhibits of Bob Christiansen, 12/2/08	
5953		Exhibit 1, notice of deposition of Johnson & Johnson	
5954		Exhibit 2, memo dated 9/24/93	
5955		Exhibit 3, memo dated 5/23/94	
5956		Exhibit 4, letter re 15-day alert ADE report	
5957		Exhibit 5, letter dated 4/25/05 and attachment	
5958		Exhibit 6, letter dated 6/20/05 and attachment	
5959		Exhibit 7, letter dated 10/4/05 and attachments	
5960		Exhibit 8, summary of activities re adverse reaction report on Kaitlyn Langstaff	
5961		Exhibit 9, cover letters for adverse drug experience reports	
5962		Exhibit 10, MedWatch report	
5963		Oral deposition and accompanying exhibits of Margarita Gardiner; 11/20/07	
5964		Exhibit 1 CV of Margarita Gardiner, 1 page	
5965		Exhibit 2 Article Bates MC064930-94	
5966		Exhibit 3 Article, Bates 00359-363	
5967		Exhibit 4 Article, Bates 00291-303	
5968		Exhibit 5 Article New England Journal of Medicine Nov. 10, 1994, pages 1272-1285	
5969		Exhibit 6 Article New England Journal of Medicine, Dec. 14, 1995, pages 1600-1607	
5970		Exhibit 7 Article December 1997, Bates 00247-249	
5971		Exhibit 8 Article, Bates 00222-225	
5972		Exhibit 9 Article November, 2001, Bates 0226-235	
5973		Exhibit 10 Article January, 2002, Bates 00216-221	
5974		Exhibit 11 Article JAMA, Bates 00255-259	

Exh No.	Date	Description	Defendants' Objections
5975		Exhibit 12 Article The Journal of Rheumatology pages 2234-2240 with delivery attachment form	
5976		Exhibit 13 MedWatch forms, Bates MC079449-079454 (not in numerical order)	Lacks authentication (Rule 901)
5977		Oral deposition and accompanying exhibits of Cathy Gelotte; 6/15/04	
5978		Exhibit No.1 Curriculum Vitae	
5979		Exhibit No.2 Article: Comparative Pharmacology of S-Ibuprofen and RS-Ibuprofen	
5980		Exhibit No.3 Motrin Suspension, Regulatory Copy	
5981		Exhibit No.4 Article: Clinical Pharmacokinetics of Ibuprofen	
5982		Exhibit No.5 Article: Pharmacodynamics and Pharmacokinetics of the Profens: Enantioselectivity, Clinical Implications, and Special Reference to S-Ibuprofen	
5983		Exhibit No.6 Article: Understanding the Chiral Pharmacology of Nonsteroidal Antiinflammatory Drugs in the Aryl Propionic Acid Class: S-Ibuprofen	
5984		Exhibit No.7 Article: Pharmacokinetics of S- and R-Ibuprofen in Volunteers and First Clinical Experience of S-Ibuprofen in Rheumatoid Arthritis	
5985		Oral deposition and accompanying exhibits of Cathy Gelotte; 10/20/10	
5986		Exhibit 1 Figure 1 Diagram	Lacks authentication (Rule 901)
5987		Exhibit 2 "S+Ibuprofen: The Superior -Steroidal Anti-Inflammatory"	
5988		Exhibit 3 "Inside the Isomers: The Tale Chiral Switches"	
5989		Exhibit 4 "Pharmacokinetics of S+ and R-Ibuprofen-Rheumatoid Arthritis"	
5990		Exhibit 5 "Interindividual Variability in	
5991		Exhibit 6 "Comparative Pharmacology of S+Ibuprofen and SR-Ibuprofen"	
5992		Oral deposition and accompanying exhibits of Hina Harlow; 11/6/08	
5993		VIDEOTAPE NO. 1	
5994		VIDEOTAPE NO. 2	

Exh No.	Date	Description	Defendants' Objections
5995		Exhibit 1 Correspondence containing Plaintiff's Notice of Videotaped Deposition of Hina Harlow	
5996		Exhibit 2 Curriculum Vitae	
5997		Exhibit 3 Correspondence containing: Petition	
5998		Oral deposition and accompanying exhibits of Hina Harlow; 11/20/08	
5999		Exhibit 1 Letter to Roger E. Salisbury MD from Steven K. Galson, MD, MPH	
6000		Exhibit 2 Photocopy of Motrin 40 Caplets packaging	
6001		Exhibit 3 Motrin 4 Coated Caplets packaging	
6002		Oral deposition and accompanying exhibits of Douglas Hough; 12/4/08	
6003		Exhibit 1 Notice to take deposition	
6004		Exhibit 2 Dr. Hough's curriculum vitae	
6005		Exhibit 3 Letter, November 17, 1999 from Gardine to Vernon and one sheet attachment	
6006		Exhibit 4 McNeil 15 day alert report Bates stamped LM000219 with two page attachment	
6007		Exhibit 5 labeling for Children's Motrin given to Gaines child	
6008		Exhibit 6 MedWatch report, Bates Stamped MOT00015628	
6009		Exhibit 7 MedWatch Report, Bates Stamped MC079613 and MC079629	
6010		Exhibit 8 MedWatch Report, Bates Stamped LM000214, 215 and 216	
6011		Exhibit 9 MedWatch Report, Bates Stamped MOT00012853, 15854, 15863, 15864, 15865, 15866, 15867	
6012		Oral deposition and accompanying exhibits of Kenneth Kwong; 9/24/08	
6013		VIDEOTAPE NO. 1	
6014		VIDEOTAPE NO. 2	
6015		VIDEOTAPE NO. 3	
6016		Exhibit 1 Plaintiffs' Notice of Videotaped Deposition of Kenneth Kwong	
6017		Exhibit 2 Document entitled, "Pharmacovigilance" MOT00004378 - 382	
6018		Exhibit 3 Email From: Denisco, Mary Joan To: Fung, Man-cheong, et al. Date: 3/22/2004	

Exh No.	Date	Description	Defendants' Objections
6019		Exhibit 4 E-mail From: Kwong, Kenneth To: Silber, Steven Date: 01/09/2004 MOT00004727	
6020		Exhibit 5 Research & Development Standard Operating Procedure 99-RD-PV-001 1.0 LM005810 - 815	
6021		Exhibit 6 Research & Development Standard Operating Procedure 99-RD-PV-012 1.0 LM005836 - 846	
6022		Exhibit 6A Research & Development Standard Operating Procedure 99-RD-PV-015 1.0 LM005887 - 892	
6023		Exhibit 7 Research & Development Standard Operating Procedure 99-RD-PV-015 2.0 LM005893 - 900	
6024		Exhibit 8 Research & Development Standard Operating Procedure 99-RD-PV-016 1.0 LM005901 - 905	
6025		Exhibit 9 Research & Development Standard Operating Procedure 99-RD-PV-016 2.0 LM005906 - 910	
6026		Oral deposition and accompanying exhibits of Kenneth Kwong; 11/7/08	
6027		Exhibit 1 Pharmacovigilance Training Manuel	
6028		Exhibit 2 McNeil Research & Development Standard Operating Procedure	
6029		Exhibit 3 Postmarketing Drug Safety Surveillance Review Article	
6030		Exhibit 4 Email 8/26/2003 205	
6031		Exhibit 5 Email 9/23/2003 209	
6032		Exhibit 6 Postmarketing Drug Safety Surveillance Review Article	
6033		Exhibit 7 Email 4/15/2004	
6034		Exhibit 8 Complaint Vigilance MAP for MCSP	
6035		Exhibit 9 C.V. of Kenneth C. Kwong, M.D.	
6036		Exhibit 10 McNeil Research & Development Standard Operating Procedure	
6037		Exhibit 11 Email 1/20/2004	
6038		Exhibit 12 Email 6/9/2004	
6039		Oral deposition and accompanying exhibits of Kenneth Kwong; 11/11/08	

Exh No.	Date	Description	Defendants' Objections
6040		Exhibit 1 Letter to Salisbury from Galson, with attachments	
6041		Oral deposition and accompanying exhibits of Kenneth Kwong; 12/10/08	
6042		Exhibit 13 Service Agreement	
6043		Exhibit 14 Medwatch Reports	Lacks authentication (Rule 901)
6044		Exhibit 15 Email	
6045		Exhibit 16 Email	
6046		Exhibit 17 Email	
6047		Exhibit 18 Email	
6048		Exhibit 19 Email	
6049		Exhibit 20 Email	
6050		Exhibit 21 Email	
6051		Exhibit 22 Email	
6052		Exhibit 23 Email	
6053		Exhibit 24 Email	
6054		Exhibit 25 Email	
6055		Oral deposition and accompanying exhibits of Lynn Pawelski; 9/22/08	
6056		Exhibit 1 Plaintiffs' Notice of Videotaped Deposition of Lynn Pawleski [sic]	
6057		Exhibit 2 CV of Lynn A. Pawelski	
6058		Exhibit 3 Letter to Food and Drug from Roger E. Salisbury, M.D., with attached Citizen Petition	
6059		Exhibit 4 Photocopy of Children's bottle	
6060		Oral deposition and accompanying exhibits of Lynn Pawelski; 12/9/08	
6061		Exhibit 1 RESUME	
6062		Exhibit 2 LETTER 6/1/98	
6063		Exhibit 3 LETTER 11/17/99	
6064		Exhibit 4 LETTER 3/1/04	
6065		Oral deposition and accompanying exhibits of Lynn Pawelski; 12/17/08	
6066		Exhibit 303 Literature Review	Lacks authentication (Rule 901)
6067		Exhibit 363 Time to Act on Drug Safety	Lacks authentication (Rule 901)
6068		Exhibit 364 The FDA & Drug Safety	Lacks authentication (Rule 901)
6069		Exhibit 365 FDA Responds to Institute	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
6070		Exhibit 366 Synopsis FDA Science/Mission	Lacks authentication (Rule 901)
6071		Exhibit 367 Testimony of Dr. Gail Cassell	Lacks authentication (Rule 901)
6072		Exhibit 368 FDA Science & Mission	Lacks authentication (Rule 901)
6073		Exhibit 369 483 Form	
6074		Exhibit 370 21 CFR 314.50	
6075		Exhibit 372 3/23/04 Emails	
6076		Exhibit 373 Draft Letter	
6077		Exhibit 374 4/8/04 Emails	
6078		Exhibit 375 8/31/05 Emails	
6079		Exhibit 376 12/18/98 Submission	
6080		Exhibit 377 Info Sheet, Infant's Motrin	
6081		Exhibit 378 8/19/99 Submission	
6082		Exhibit 379 7/2/02 Package Approval	
6083		Exhibit 401 Annual Report	
6084		Exhibit 402 Annual Report	
6085		Exhibit 403 Annual Report	
6086		Exhibit 404 Annual Report	
6087		Exhibit 405 Annual Report	
6088		Exhibit 406 Annual Report	
6089		Exhibit 407 Annual Report	
6090		Exhibit 407A Annual Report	
6091		Exhibit 408 Annual Report	
6092		Exhibit 410 Annual Report	
6093		Exhibit 419 ADE Report	
6094		Exhibit 420 ADE Report	
6095		Exhibit 421 ADE Report	
6096		Exhibit 422 ADE Report	
6097		Exhibit 423 ADE Report	
6098		Exhibit 424 ADE Report	
6099		Exhibit 501 Article	
6100		Exhibit 502 Article	
6101		Exhibit 503 Article	
6102		Exhibit 504 Article	
6103		Exhibit 505 Article	
6104		Exhibit 506 Article	
6105		Exhibit 507 Article	
6106		Exhibit 508 Article	
6107		Exhibit 509 Article	
6108		Exhibit 510 Article	
6109		Exhibit 511 Article	

Exh No.	Date	Description	Defendants' Objections
6110		Exhibit 512 Article	
6111		Exhibit 513 Article	
6112		Exhibit 514 Article	
6113		Exhibit 515 Article	
6114		Exhibit 516 Article	
6115		Exhibit 517 Article	
6116		Exhibit 518 Article	
6117		Exhibit 519 Article	
6118		Exhibit 520 Article	
6119		Exhibit 521 Article	
6120		Exhibit 522 Article	
6121		Exhibit 523 Article	
6122		Exhibit 524 Article	
6123		Exhibit 525 Article	
6124		Exhibit 526 Article	
6125		Exhibit 527 Article	
6126		Exhibit 528 Article	
6127		Oral deposition and accompanying exhibits of Lynn Pawelski; 4/22/09	
6128		Exhibit 1 Notice of Deposition and Document Request	
6129		Exhibit 2 Resume (Lynn Pawelski)	
6130		Exhibit 3 E-mails (Pawelski - Denisco)	
6131		Exhibit 4 Code of Federal Regulations 21, Parts 200 to 299 (2003)	
6132		Exhibit S Wyeth Opinion Document (Pages 11 and 12) 182	
6133		Exhibit 6 Letter (Carol L Krueger)	
6134		Exhibit 7 Documents Bates Numbers MC064409 - MC064448	
6135		Exhibit 8 9/13/04 E-mail (Beth Gaffney)	
6136		Exhibit 9 Documents Bates Numbers MOT00008748 - MOTO0008783	
6137		Oral deposition and accompanying exhibits of Lynn Pawelski; 6/22/10	
6138		Exhibit 1 Notice To Take Videotaped Deposition of Defendant's Corporate Representative(s)	
6139		Exhibit 2 Ibuprofen Oral Suspension USP label, Bates stamped ALP034912 through ALP034928	
6140		Exhibit 3 Packet of documents, 18 pages	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
6141		Exhibit 4 McNeil Failure to File/Report Scientific Literature in NDAs and Postmarketing reports for Motrin Products	Lacks authentication (Rule 901)
6142		Exhibit 5 Article entitled "Practical Considerations in Developing an Automated Signaling Program within a Pharmacovigilance Department"	
6143		Exhibit 6 Letter dated June 22, 2006 to Roger E. Salisbury, MD from Steven K. Galson, MD, MPH	
6144		Oral deposition and accompanying exhibits of Laura Plantz; 6/15/04	
6145		Exhibit No. 1 Notice of Deposition	
6146		Exhibit No. 2 Children's Motrin Ibuprofen Oral Suspension Q & A's	
6147	7/14/2001	Exhibit No. 3 MedWatch Report, 7/14/2001	
6148		Exhibit No. 4 Table of Subjects Treated with Ibuprofen in McNeil Clinical Trial Reporting Adverse Event COSTART Terms	
6149		Exhibit No. 5 1993 First and Second Quarter Adverse Drug Experience Reports	
6150	4/7/2002	Exhibit No. 6 MedWatch Report, 4/7/2002	Lacks authentication (Rule 901)
6151		Exhibit No. 7 Curriculum Vitae	
6152	10/2/2007	Oral deposition and accompanying exhibits of Sandra Shoenwald; 10/2/07	
6153		Exhibit 1 Notice	
6154		Exhibit 2 CV	
6155		Exhibit 3 PDR excerpt	
6156	6/22/2006	Exhibit 4 6/22/06 Letter	
6157		Exhibit 5-28 SOPs	
6158	9/23/2008	Oral deposition and accompanying exhibits of Sandra Shoenwald; 9/23/08	
6159		VIDEOTAPE NO. 1	
6160		VIDEOTAPE NO. 2	
6161		VIDEOTAPE NO. 3	
6162		Exhibit 1 Plaintiffs' Notice of Videotaped Deposition of Sandra Schoenewald	
6163		Exhibit 2 Curriculum Vitae Sandra Lewis Schoenewald, PharmD	
6164		Exhibit 3 Research and Development Standard Operating Procedure 99-RD-MA-012 2.0 LM005676 - 687	

Exh No.	Date	Description	Defendants' Objections
6165	12/16/2008	Oral deposition and accompanying exhibits of Sandra Shoenwald; 12/16/08	
6166		Exhibit 301 Notice of Deposition	
6167		Exhibit 302 E-Mails 12	
6168		Exhibit 303 Literature Review	
6169		Exhibit 304 Federal Register	
6170		Exhibit 305 E-Mails	
6171		Exhibit 306 Compliant Vigilance Map	
6172	7/23/2001	Exhibit 307 Memo Dated 7/23/01	
6173		Exhibit 308 Sign-in Sheet	
6174		Exhibit 309 E-Mail dated 10/16/03	
6175		Exhibit 310 Three-Page Excerpt	Lacks authentication (Rule 901)
6176	10/16/2003	Exhibit 311 E-Mail Dated 10/16/03	
6177		Exhibit 312 E-Mails	
6178		Exhibit 313 E-Mails	
6179		Exhibit 314 E-Mails	
6180		Exhibit 315 E-Mails	
6181		Exhibit 316 FDA Spontaneous Reporting Reports	
6182		Exhibit 317 Document (Retained by Counsel)	Lacks authentication (Rule 901)
6183		Exhibit 318 Zundel Complaint	
6184		Exhibit 319 MedWatch Report	
6185		Exhibit 320 MedWatch Report	
6186		Exhibit 321 MedWatch Report	
6187		Exhibit 322 MedWatch Report	
6188		Exhibit 323 MedWatch Report	
6189		Exhibit 324 MedWatch Report	
6190		Exhibit 325 MedWatch Report	
6191		Exhibit 326 MedWatch Report	
6192		Exhibit 327 MedWatch Report	
6193		Exhibit 328 MedWatch Report	
6194		Exhibit 329 MedWatch Report	
6195		Exhibit 330 MedWatch Report	
6196		Exhibit 331 MedWatch Report	
6197		Exhibit 332 MedWatch Report	
6198		Exhibit 333 MedWatch Report	
6199		Exhibit 334 MedWatch Report	
6200		Exhibit 335 MedWatch Report	
6201		Exhibit 336 MedWatch Report	
6202		Exhibit 337 MedWatch Report	
6203		Exhibit 338 MedWatch Report	

Exh No.	Date	Description	Defendants' Objections
6204		Exhibit 339 MedWatch Report	
6205		Exhibit 340 MedWatch Report	
6206		Exhibit 341 MedWatch Report	
6207		Exhibit 342 MedWatch Report	
6208		Exhibit 343 MedWatch Report	
6209		Exhibit 344 MedWatch Report	
6210		Exhibit 345 MedWatch Report	
6211		Exhibit 346 MedWatch Report	
6212		Exhibit 347 Fax Dated 3/1/05 w/Attachments	
6213		Exhibit 348 Transmittal Form	
6214		Exhibit 349 Transmittal Form	
6215		Exhibit 350 15-Day Alert Cover Sheet	
6216		Exhibit 351 MedWatch Report	
6217		Exhibit 352 Case Report	
6218		Exhibit 353 MedWatch Report	
6219		Exhibit 354 MedWatch Report	
6220		Exhibit 355 MedWatch Report	
6221		Exhibit 356 MedWatch Report	
6222		Exhibit 357 MedWatch Report	
6223		Exhibit 358 MedWatch Report	
6224		Exhibit 359 Review Article	
6225		Exhibit 360 Review Article	
6226		Exhibit 361 Concept Paper	Lacks authentication (Rule 901)
6227		Exhibit 362 STAR Published Literature Database	Lacks authentication (Rule 901)
6228	4/21/2009	Oral deposition and accompanying exhibits of Sandra Shoenwald; 4/21/09	
6229		Exhibit-1 Deposition Notice	
6230		Exhibit-2 Resume	
6231		Exhibit-3 Individual Responsibilities Document	Lacks authentication (Rule 901)
6232		Exhibit-4 483 Document	
6233	4/14/2006	Exhibit-5 Document dated 4/14/06	
6234		Exhibit-6 Document	Lacks authentication (Rule 901)
6235	7/19/1999	Exhibit-7 July 19th, 1999 Memo	
6236		Exhibit-8 Annual Report to NDA 20-516	
6237	2003	Exhibit-9 2003 Physician's Desk Reference	
6238	2003	Exhibit-10 2003 Adverse Event Reports	Lacks authentication (Rule 901)
6239		Exhibit-11 Set of E-mails	
6240		Exhibit-12 E-mails 282	

Exh No.	Date	Description	Defendants' Objections
6241		Exhibit-13 Series of E-mails	
6242		Exhibit-14 November 3rd, 2005 E-mail	
6243		Exhibit-15 Document Bates No. MOT0007450	
6244		Exhibit-16 Binder of SOPs	
6245	2006	Exhibit-17 2006 Physician's Desk Reference	
6246		Exhibit-18 Motrin 2003 Prescription Information	
6247	5/13/2008	Oral deposition and accompanying exhibits of Sandra Shoenwald; 5/13/08	
6248		Exhibit 1 Curriculum Vitae	
6249		Exhibit 2 Standard Operating Procedure "Adverse Drug Experience Reporting"	
6250		Exhibit 3 Standard Operating Procedure "Determining Expectedness of Adverse Event Reports"	
6251		Exhibit 4 Standard Operating Procedure "Procedure for Review of Adverse Event Surveillance and Safety Signals by the McNeil Safety Review Committee"	
6252		Exhibit 5 Standard Operating Procedure "Procedures for Exchange of Safety Information Between McNeil CPC and Pharmacia & Upjohn (PNU) for OTC ibuprofen containing products and Rx Motrin"	
6253		Exhibit 6 Standard Operating Procedure "Adverse Event/Adverse Drug Experience Reporting"	
6254		Exhibit 7 Standard Operating Procedure "Corrective Action for Late Submissions"	
6255		Exhibit 8 Standard Operating Procedure "Identifying and Reporting Adverse Events (AEs) from the Medical Literature"	
6256		Exhibit 9 Standard Operating Procedure "Obtaining Follow-up Information on Spontaneous Adverse Event(s)"	
6257		Exhibit 10 Standard Operating 219 Procedure "Adverse Experience Monitoring Process"	
6258	4/4/2003	Exhibit 11 Memo dated April 4, 2003, Bates stamped MOT00007450	
6259		Exhibit 12 E-mail dated 02/11/2005, Bates stamped MOT00007316.1	
6260		Exhibit 13 E-mail dated 05/02/2006, Bates stamped MOT00007455.12	

Exh No.	Date	Description	Defendants' Objections
6261	12/8/2005	Exhibit 14 E-mail dated 12/08/2005 MOT00007148.6	
6262	12/8/2005	Exhibit 15 E-mail dated 12/08/2005 MOT00007148.4	
6263	10/21/2008	Oral deposition and accompanying exhibits of Steven Silber; 10/21/08	
6264		Exhibit 1 Plaintiffs' Second Amended Notice of Videotaped Deposition of Steven Silber	
6265		Exhibit 2 Curriculum Vitae of Steven A. Silber, MD, FACP	
6266	4/2/09	Oral deposition and accompanying exhibits of Steven Silber; 4/2/09	
6267		Exhibit 1, CV	
6268	2004	Exhibit 2, e-mail from you to Kenneth Kwong in December '04	
6269	10/1/2003	Exhibit 3, McNeil e-mail dated October 1, 2003	
6270	3/26/2003	Exhibit 4, e-mail dated March 26, 2003	
6271		Exhibit 5, e-mail	
6272		Exhibit 6, e-mail	
6273		Exhibit 7, "Department of human health"	
6274		Exhibit 8, over-the-counter version	Lacks authentication (Rule 901)
6275		Exhibit 9, letter from the FDA to McNeil	
6276		Exhibit 10, e-mail	
6277		Exhibit 11, Standby Statement	
6278		Exhibit 12, string of e-mails	
6279		Exhibit 13, e-mail	
6280		Exhibit 14, e-mail	
6281		Exhibit 15, MOT 0001153	
6282		Exhibit 16, adverse event database	Lacks authentication (Rule 901)
6283	1/8/2008	Oral deposition and accompanying exhibits of Ardith Talbot; 1/8/08	
6284		Exhibit 1 Curriculum Vitae	
6285		Exhibit 2 Document	
6286		Exhibit 3 Document	
6287	2009	Oral deposition and accompanying exhibits of Mike Hoehn, 12.09	
6288		Exhibit 1, Notice	
6289		Exhibit 2, CV	
6290		Exhibit 3, Trade & Gov't Memos	
6291	5/31/1984	Exhibit 4, Hammes to Robert Temple, 5/31/84	

Exh No.	Date	Description	Defendants' Objections
6292	11/6/1995	Exhibit 5, email 11/6/95 from Perkins, lets politely keep pressing for the meeting ASAP	
6293		Exhibit 6, Pagusuyin Approval letters memo	
6294	11/8/1994	Exhibit 7, McNeil Record of Contact 11/8/94	
6295	11/14/1994	Exhibit 8, Chester Memo 11/14/94	
6296	10/31/1994	Exhibit 9, Denisco change name memo 10/31/94	
6297	7/13/1995	Exhibit 10, DDMAC letter 7/13/95	
6298		Exhibit 11, Pagsuyuin Memo re CM Professional Materials	
6299		Exhibit 12, Pagsuyuin Memo re Pediatric Approval	
6300	11/20/1995	Exhibit 13, Reel Memo 11/20/95	
6301	3/21/1995	Exhibit 14, Memo to Professional Sales Force, Focus on BU 3/21/95	
6302	3/22/1995	Exhibit 15, Memo from Information Center, 3/22/95, re Slone Study News	
6303	1/18/1996	Exhibit 16, A comprehensive review of the Safety of Ibu in Ped Pts, by Una Kistner for Michael Hoehn, 1/18/96	
6304	2/27/1996	Exhibit 17, Ibuprofen Clinical Monograph from Kistner to Hoehn, 2/27/96	
6305	4/18/1996	Exhibit 18, BU Study Addendum to Professional Sales Force 4/18/96	
6306	7/10/96	Exhibit 19, Ibuprofen Clinical Monograph from Kistner to Hoehn 7/10/96	
		Exhibits from Johnson v. Johnson & Johnson	
6300	1983	8/12/1983 Korberly Report - Ibuprofen Review - Sabrina v J&J Plaintiff's Exhibit 45	
6301	1983	7/28/1983 McNeil Letter to Collins re: Rx to OTC Switch of Ibuprofen (Motrin) - Sabrina v J&J Plaintiff's Exhibit 55	
6302	1991	Patient Data Listing for Sutdy 90-056 Children's Motrin Suspension 12/10/1991 - Sabrina v J&J Plaintiff's Exhibit 151	
6303	1991	Patient Data Listing for Sutdy 90-056 Children's Motrin Suspension 12/10/1991 - Sabrina v J&J Plaintiff's Exhibit 152	
6304	1992	Data Listing for Protocol 90-056, 1991-92 - Sabrina v J&J Plaintiff's Exhibit 153	
6305	1993	12/22/1993 Clinical Study report Protocol 90-056 - Sabrina v J&J Plaintiff's Exhibit 82	

Exh No.	Date	Description	Defendants' Objections
6306	1994	Children's Motrin Advertising Materials through 1994- Sabrina v J&J Plaintiff's Exhibit 217A-E	Lacks authentication (Rule 901)
6307	1994	Trade and Government Memo MC066971 - Sabrina v J&J Plaintiff's Exhibit 48	
6308	1995	5/9/95 FDA/DDMAC Letter to Pagsuyuin - Sabrina v J&J Plaintiff's Exhibit 110	
6309	1995	6/14/95 Letter from Pagsuyuin - Sabrina v J&J Plaintiff's Exhibit 111	
6310	1995	6/16/1995 FDA Letter to Pagsuyuin re: NDA 20-516 - Sabrina v J&J Plaintiff's Exhibit 112	
6311	1995	2/27/95 Statistical Review and Evaluation - Sabrina v J&J Plaintiff's Exhibit 80	
6312	1995	Children's Motrin Ibuprofen: Rx to OTC Switch 1995 - Sabrina v J&J Plaintiff's Exhibit 81	
6313	1997	4/1/1997 Letter from Pagsuyuin re: Rx Pediatric Motrin Labeling - Sabrina v J&J Plaintiff's Exhibit 108	
6314	1998	March 31, 1988 McNeil Letter to FDA re: NDA Ibuprofen Pediatric Suspension 80mg/mL - Sabrina v J&J Plaintiff's Exhibit 218	
6315	2003	Mockenhaupt, M., et al., J Rheumatol, "The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Antiinflammatory Drugs: A Multinational Perspective", 30: 2234-40, (2003) - Sabrina v J&J Plaintiff's Exhibit 65	
6316	2003	3/26/2003 Email from Temple re: Standby Statement for Children's Motrin and Stevens Johnson Syndrome/toxic Epidermal Necrolysis - Sabrina v J&J Plaintiff's Exhibit 67	
6317	2003	4/21/03 Email from temple re Ovid Citations for Stevens Johnson Syndrome and Ibuprofen or NSAIDs - Sabrina v J&J Plaintiff's Exhibit 68	
6318	2003	10/1/03 Email from Volpe - Sabrina v J&J Plaintiff's Exhibit 69	
6319	2004	9/8/04 Adverse Event Routing Form - Sabrina v J&J Plaintiff's Ex. 88	
6320	2004	Dolormin for Children Foreign Labeling 2004 - Sabrina v J&J Plaintiff's Exhibit 113	Lacks authentication (Rule 901)
6321	2004	Dolormin Ibuprofen Juice Label 2004 - Sabrina v J&J Plaintiff's Exhibit 52	Lacks authentication (Rule 901)
6322	2004	9/12/04 Goldfrank report - Sabrina v J&J Plaintiff's Exhibit 53	

Exh No.	Date	Description	Defendants' Objections
6323	2005	12/1/2005 McNeil Standard Operating Procedure - Procedure for Review of Adverse Event Surveillance and Safety Signals by the McNeil Safety Review Committee - Sabrina v J&J Plaintiff's Exhibit 119	
6324	2005	Reviewer Guidance Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review - 2/2005 - Sabrina v J&J Plaintiff's Exhibit 237	Lacks authentication (Rule 901)
6325	2005	2/11/05 Email from Leebaw - Sabrina v J&J Plaintiff's Exhibit 71	
6326	2005	3/7/05 Email from Clymer - Sabrina v J&J Plaintiff's Exhibit 72	
6327	2006	6/22/06 Citizen's Petition 2005-0072/CP1 - Sabrina v J&J Plaintiff's Ex. 79	
6328	2006	1/11/06 - McNeil Research and Development - Procedures for Exchange of Safety Information Between McNeil CPC and Pharmaciaa & Upjohn (PNU) for OTC Ibuprofen containing products andRx Motrin - Sabrina v J&J Plaintiff's Exhibit 120	
6329	2007	Adverse Drug Event Reports & Medwatch Forms 1997-2007 - Sabrina v J&J Plaintiff's Exhibit 142	Lacks authentication (Rule 901)
6330	2007	1/20/2007 - Motrin Ibuprofen Tablets Label - Sabrina v J&J Plaintiff's Exhibit 222	
6331		MCNEIL'S RESPONSE TO FDA'S PROPOSED LABELING FOR OTC NONSTEROIDAL ANTI-INFLAMMATORY DRUG (NSAID) PRODUCTS - Sabrina v J&J Plaintiff's Ex. 84	
6332		Video of Children's Motrin Commercial - Sabrina v J&J Plaintiff's Exhibit 217F	
6333	1987	8/31/1987 Motrin NDA 17-463 Supplement to Allow OTC Marketin og 300mg Vol 2/2 - Defense Exhibit 263	
6334	1989	1989 Medical Officer Review NDA 19-842 - Defense Exhibit 2294	
6335	1989	9/19/89 FDA Letter to McNeil - Defense Exhibit 2303	
6336	1990	12/20/90 An Assessment of the Safety of Pediatric Ibuprofen - Defense Exhibit 2007	
6337	1990	1/29/90 McNeil Letter - Defense Exhibit 2082	

Exh No.	Date	Description	Defendants' Objections
6338	1995	6/16/95 Letter from FDA - Defense Exhibit 2005	
6339	1995	3/2/95 FDA Fax to Pagsuyuin - Defense Exhibit 2075	
6340	1995	3/28/95 background Materils for Arthritis and Nonprescription Drugs AdComm Meeting - Defense Exhibit 2077	
6341	1995	6/26/95 Letter to Raymond - Defense Exhibit 2275A	
6342	1995	6/14/95 Letter from Pagsuyuin - Defense Exhibit 2275B	
6343	1995	6/22/95 McNeil Letter to Shnitzler - Defense Exhibit 2275C	
6344	1999	4/8/99 CDER Fax - Defense Exhibit 2089	
6345	2000	10/2/200 Let to FDA - Defense Exhibit 2004	
6346	2000	10/2/00 - Children's Motrin Label Berry Flavor - Defense Exhibit 2004	
6347	2001	2002 Children's Motrin Berry Flavored Oral Suspension Packing Label - Defense Exhibit 2001	
6348	2004	11/16/04 NDA 19-842 Annual Report NO. 15 - Defense Exhibit 264	
6349	2004	6/8/04 Email from Ken and Joan Johnson - Defense Exhibit 2162	
6350	2004	NDA 19-842 2003-2004 Annual report Vol 1/2 - Defense Exhibit 2273A	
6351	2004	NDA 19-842 2003-2004 Annual report Vol 2/2 - Defense Exhibit 2273B	
6352	2005	5/2/05 Email from Wiley - Defense Exhibit 2193	
6353	2005	Supplemental Labeling Request CBE Form 2005 - Defense Exhibit 2276-19	
6354	2005	Supplemental Labeling Request CBE Form 2005 - Defense Exhibit 2276-20	
6355	2005	12/7/2005 FDA Letter to Mcneil - Defense Exhibit 2276-22	
6356	2007	11/13/2007 CV of Dr. Stern - Defense Exhibit 265	
6357		Joan Johnson Story of Sabrina's SJS - Defense Exhibit 2217	
6358		Def Exp Rep of Lawrence Eichenfeld	
6359		Def Exp Rep of Carl Peck	
6360		Def Exp Rep of Laurentius Marais	
6361		Def Exp Rep of Merlin Wilson	

Exh No.	Date	Description	Defendants' Objections
6362		Def Exp Rep of Stanford Shulman	
6363		Def Exp Rep of Dr. Weisman	
6364		All exhibits identified by defendants in this case	Lacks authentication (Rule 901)
6365		All exhibits identified by defendants in Maya, et ux. v. J&J, et al., PCCP, Feb. Term 2009, No. 002879; which were served on or about 3/2/11 in Defendants' Second Amended Exhibit List (excluding the medical and educational records of Brianna Maya). All such exhibits will be numbered according to the following example: DX1125 is Nelson's Textbook of Pediatrics 2000 (16th Ed), that would be PX 6364.1125.	Lacks authentication (Rule 901)
6366		All demonstrative aides identified or used by the defendants	Lacks authentication (Rule 901)
7000		Deposition of James B. Hoyme, M.D.	
7001		Exhibit 1- Amended Notice of Deposition	
7002		Exhibit 2- MMPI-2 Basic Service Report	
7003		Exhibit 3- Invoice for services	
7004		Exhibit 4- Fee Schedule	
7005		Exhibit 5- Expert Report of James B. Hoyme, M.D.	
7006		Exhibit 6- Records from University Neurology	
7007		Exhibit 7- Records from Steven Zuckerman, M.D.	
7008		Exhibit 8- Records from Owen Scott, Ph.D.	
7009		Exhibit 9- C.V. of James Hoyme, M.D.	
7010		Exhibit 10- Neuropsychological Evaluation performed March 10, 2010 and Expert Report of William Bruce Jones, M.D.	
7011		Exhibit 11- Report and C.V. of Jonathan Walker, M.D.	
7012		Deposition of Phillip Rosenthal, M.D.	
7013		Exhibit 1- Expert Report of Phillip Rosenthal, M.D.	
7014		Exhibit 2- C.V. of Phillip Rosenthal, M.D. dated 11/5/09	
7015		Exhibit 3- List of Ibuprofen and Hepatotoxicity Research	
7016		Exhibit 4- Amended Notice of Deposition	
7017		Exhibit 5- C.V. of Phillip Rosenthal, M.D. dated 6/6/10	

Exh No.	Date	Description	Defendants' Objections
7018		Exhibit 6- Various progress notes of Maureen Jonas, M.D.	
7019		Exhibit 7- Case Report: "Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child."	
7020		Exhibit 8- Article, "Vanishing Bile Duct Syndrome Temporally Associated with Ibuprofen Use"	
7021		Exhibit 9- Article, "Idiosyncratic Liver Toxicity of Nonsteroidal Antiinflammatory Drugs: Molecular Mechanisms and Pathology."	
7022		Exhibit 10- Article, "Drug-Induced Hepatic Injury: An Analysis of 1100 cases reported to the Danish Committee on Adverse Drug Reactions Between 1978 and 1987"	
7023		Exhibit 11- Article, "Hepatotoxicity of Analgesics and Anti-Inflammatory Agents"	
7024		Exhibit 12- Article, "Nonsteroidal Anti-Inflammatory Drug-Induced Hepatic Disorders Incidence and Prevention."	
7025		Exhibit 13- Article, "Hepatocellular Damage from Non-Steroidal Anti-Inflammatory Drugs"	
7026		Exhibit 14- Article, "Hepatotoxicity of Nonsteroidal Anti-Inflammatory Drugs"	
7027		Exhibit 15- Article, "Acute Vanishing Bile Duct Syndrome After Ibuprofen Therapy in a Child"	
7028		Exhibit 16- Article, "Hepatotoxicity Associated with Non-Steroidal Anti-Inflammatory Drugs"	
7029		Exhibit 17- Article, "Quantitative Studies of the Risk of Serious Hepatic Injury in Persons Using Nonsteroidal Antiinflammatory Drugs."	
7030		Exhibit 18- Article, "Updated of Hepatotoxicity Due to Classes of Drugs in Common Clinical Use: Non-Steroidal Drugs, Anti-Inflammatory Drugs, Antibiotics, Antihypertensives and Cardiac and Psychotropic Agents"	
7031		Exhibit 19- Article, "Drug-Induced Liver Disease"	
7032		Exhibit 20- Article, "Cholestatic Liver Injury Due to Ibuprofen"	
7033		Exhibit 21- Article, "Orthotopic Liver Transplantation After Subacute Liver Failure Induced by Therapeutic Doses of Ibuprofen"	

Exh No.	Date	Description	Defendants' Objections
7034		Exhibit 22- Article, "Subfulminant Hepatitis Requiring Liver Transplantation Following Ibuprofen Overdose."	
7035		Exhibit 23- Article, "Acute Vanishing Bile Duct Syndrome After Ibuprofen Therapy in a Child."	
7036		Exhibit 24- Article, "Vanishing Bile Duct Syndrome Temporally Associated with Ibuprofen Use."	
7037		Exhibit 25- Article, "Stevens-Johnson Syndrome and Cholestatic Hepatitis."	
7038		Exhibit 26- Article, "Unusual Manifestation of Stevens-Johnson Syndrome Involving the Respiratory and Gastrointestinal Tract."	
7039		Exhibit 27- Article, "Ibuprofen-Induced Hypersensitivity Syndrome."	
7040		Exhibit 28- Article, "Drugs Associated with Hepatotoxicity and their Reporting Frequency of Liver Adverse Events in Vigibase."	
7041		Exhibit 29- Case Report: "Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child."	
7042		Exhibit 30- List of Prior Testimony	
7043		Deposition of George Samaras, Ph.D.	
7044		Exhibit 1- Amended Notice of Deposition	
7045		Exhibit 2- C.V. of George Samaras, Ph.D. (11 pages)	
7046		Exhibit 3- C.V. of George Samaras, Ph.D. (12 pages)	
7047		Exhibit 4- Samaras timesheet	
7048		Exhibit 5- CD created by George Samaras, Ph.D.	
7049		Exhibit 6- CD of media files reviewed by George Samaras, Ph.D.	
7050		Exhibit 7- CD of McNeil advertisements, media plans, and distribution lists	
7051		Exhibit 8- CD of Depositions and Exhibits from other cases against McNeil	
7052		Exhibit 9- Article by George Samaras, Ph.D.- The Use, Misuse and Abuse of Design Controls	
7053		Exhibit 10- Article by George Samaras, Ph.D.- Using Human-Centered Systems Engineering to Reduce Nuse Stakeholder Dissonance	

Exh No.	Date	Description	Defendants' Objections
7054		Exhibit 11- excerpt from Woodson, Tillman and Tillman, Human Factors Design Handbook, Second Ed.	
7055		Exhibit 12- Expert report of George Samaras, Ph.D. with notes	
7056		Exhibit 13- Expert report of George Samaras, Ph.D.	
7057		Exhibit 14- Amended Notice of Deposition of George Samaras, Ph.D.	
7058		Exhibit 15- Letter from Messa & Associates enclosing CD of documents	
7059		Exhibit 16- Index of Depositions and Exhibits from other cases against McNeil	
7060		Exhibit 17- Mary Joan Denisco Deposition with attached exhibits from Wolfe v. McNeil	
7061		Exhibit 18- Deposition of Peter Bell with attached exhibits from Wolfe v. McNeil	
7062		Exhibit 19- BUFS Draft of Final Report	
7063		Exhibit 20- 12/20/90- Protocol: An Assessment of the Safety of Pediatric Ibuprofen	
7064		Exhibit 21- Ibuprofen: An Analysis of Safety and Efficacy	
7065		Exhibit 22- 12/22/93-McNeil Consumer Products Company-Clinical Study Report- Phase IV- An Assessment of the Safety of Pediatric Ibuprofen	
7066		Deposition of Margaret Fisher, M.D.	
7067		Exhibit 1- C.V. of Margaret Fisher	
7068		Exhibit 2- Defense Expert Report of Margaret Fisher	
7069		Exhibit 3- Information Regarding Expert Witness Experience	
7070		Exhibit 4- Letter to defense counsel regarding costs for services	
7071		Exhibit 5- Handwritten Notes of Margaret Fisher	
7072		Exhibit 6- Case Report: "Drug-Associated Acute-Onset Vanishing Bile Duct and Stevens-Johnson Syndromes in a Child."	
7073		French L. Toxic epidermal necrolysis and Stevens Johnson Syndrome: Our current understanding. Allergology International 2006;55:9-16.	

Exh No.	Date	Description	Defendants' Objections
7074		Stevens A, Johnson F. A new eruptive fever associated with stomatitis and ophthalmia: Report of two cases in children. American Journal of Diseases of Children. 1922;24:526-533.	
7075		Lyell A. Toxic epidermal necrolysis: An eruption resembling scalding of the skin. British Journal of Dermatology. 1956;68(11):355-361.	
7076		Merck. Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). In: Rehmus W, ed. Merck online manual. Vol. 2010; 2009.	
7077		Roujeau J, Stern R. Severe Adverse Cutaneous Reactions to Drugs. The New England Journal of Medicine. 1994;331(19):1272-1285.	
7078		Goldstein S, Wintroub B, Elias P, Wuepper K. Toxic epidermal necrolysis: un-muddying the waters. Archives of Dermatology. 1987;123:1153-1156.	
7079		Stern R, Bigby M. An expanded profile of cutaneous reactions to nonsteroidal anti-inflammatory drugs: Reports to a specialty-based system for spontaneous reporting of adverse reactions to drugs. JAMA. 1984;252(11):1433-1437.	
7080		Huckisson EC. Seminars in arthritis and rheumatism. Antiinflammatory Drugs. 1977; VII(1):1-20.	
7081		Rousseau G, Lamson N, Rogers W. Designing Warnings to Compensate for Age-Related Changes in Perceptual and Cognitive Abilities. Psychology and Marketing. 1998; 15(7):643-662.	
7082		Rogers W, Rousseau G, Lamson N. Maximizing the Effectiveness of the Warning Process: Understanding the Variables that Interact with Age. In: Morrell R, Park D, eds. Aging and Medication Information Processing; 1998.	
7083		Laughery K, Hammond A. Overview. In: Wogalter M, DeJoy D, Laughery K, eds. Warnings and Risk Communication. London/Philadelphia: Taylor and Francis;; 1999:3-12.	

Exh No.	Date	Description	Defendants' Objections
7084		Wogalter M, Laughery K. Warning! Sign and Label Effectiveness. Current Directions in Psychological Science. 1996;5:33-37.	
7085		DeJoy D. A Revised Model of the Warnings Process Derived from Value-Expectancy Theory. Human Factors Society 22nd Annual Meeting. Santa Monica, CA Human Factors Society; 1991: 1043-1047.	
7086		Lehto M, Miller J. The Effectiveness of Warning Labels. Journal of Products Liability. 1988;11:225-270.	
7087		Rogers W, Lamson N, Rousseau G. Warning research: An integrative perspective. Human Factors. 2000;42(1):102-139.	
7088		de la Fuente J, Bix L. A proposed framework for understanding human-package interactions. Packaging Technology and Science. East Lansing, MI: Michigan State University; 2010.	
7089		Lumpkin J, Strutton D, Lim C, Lowrey S. A shopping orientation based prescription for the treatment of OTC medication misuse among the elderly. Health Marketing Quarterly. 1990;8(1/2):95-110.	
7090		Weisman R, Howland M, Goldfrank L. Ibuprofen: An analysis of safety and efficacy. August 1984.	
7091		Marasco W, Gikas P, Azziz-Baumgartner R, Hyzy R, Eldredge C, Stross J. Ibuprofen-Associated Renal Dysfunction: Pathophysiologic Mechanisms of Acute Renal Failure, Hyperkalemia, Tubular Necrosis, and Proteinuria. Archives of Internal Medicine. 1987;147:2107-2116.	
7092		Poirer TI. Reversible renal failure associated with Ibuprofen: Case report and review of the literature. Drug Intelligence and Clinical Pharmacy. 1984; 18:27-32.	
7093		Schneider PD. Nonsteroidal anti-inflammatory drugs and acute cortical necrosis. Annals of Internal Medicine. 1986; 105:303-304.	

Exh No.	Date	Description	Defendants' Objections
7094		McIntire S, Rubenstein R, Gartner J. Acute flank pain and reversible renal dysfunction associated with nonsteroidal anti-inflammatory drug use. Pediatrics. 1993;92:459-460.	
7095		Shelley ED. Ibuprofen urticaria. Journal of the American Academy of Dermatology. 1987;17:1057-1058.	
7096		Kantor TG. Ibuprofen. Annals of Internal Medicine. 1979;91:877-882.	
7097		Bastuji-Garin S, Fouchar N, Bertochii M, Roujeau J, Revuz J, Wolkenstein P. SCORTEN: A Severity-of-Illness Score for Toxic Epidermal Necrolysis. The Society for Investigative Dermatology. 2000;115(2): 149-153.	
7098		Expert Report and C.V. of Lorraine E. Buchanan, RN, MSN, CRRN	
7099		Kiley Wolfe's medical records	
7100		Deposition transcripts from Wolfe v. McNeil	
7101		Various billing records (Cincinnati Children's Hospital, CVS Pharmacy, Neuromedical Center, Baton Rouge Clinic, The Psychology Clinic, Blue Cross/Blue Shield of Louisiana Claims summary reports).	
7103		United States Life Tables	Lacks authentication (Rule 901)
7104		Expert Report and C.V. of Royal Bunin, MBA	
7105		Expert Report and C.V. of Marvin E. Goldberg, Ph.D.	
7106		Association of American Medical Colleges (AAMC) "Industry Funding of Medical Education; Report of an AAMC Task Force," (2008); www.aamc.org/publications	
7107		Brennan et al. (2006) "Health Industry Practices That Create Conflicts of Interest, JAMA (Jan. 23) 429-433.	
7108		National Council of Patient Information and Education (NCPIE) 2002 "Attitudes and Beliefs About the Use of Over-the-Counter Medicines: A Dose of Reality; A National Survey of Consumers and Health Professionals" www.harrisinteractive.com	

Exh No.	Date	Description	Defendants' Objections
7109		Vredenburg, AG & Zackowitz, IB, "Expectations;" Ch. 25 in MS Wogalter, ed. (2006) "Handbook of Warnings," Lawrence Erlbaum Associates: Mahwah NJ, London.	
7110		Wogalter, MS, Godfrey SS, Fontenelle, GA, Desaulniers, DR, Rothstein, PR and Laughery, KR (1987) "Effectiveness of warnings." Human Factors, 29, 599-612; (see reference to this finding in Wogalter, MS, DeJoy, DM and Laughery, KR (eds.) (1999) "Warnings and Risk Communication," Taylor & Francis: London, Philadelphia).	
7111		Wogalter, MS. et al. (1991) "Consumer Product Warnings: The Role of Hazard Perception," Journal of Safety Research, 22, 71-82).	
7112		Ross, Kenneth, Journal of Products Liability, "Legal and Practical Considerations for the Creation of Warning Labels and Instruction Books," Vol. 4, pp. 29-45.	
7113		1996 PDR for Nonprescription Drugs and Dietary Supplements	Lacks authentication (Rule 901)
7114		FDA Response to Petition for Reconsideration	
7115		Documents regarding "Beat Advil Program"	Lacks authentication (Rule 901)
7116		McNeil Sales Materials	Lacks authentication (Rule 901)
7117		McNeil Marketing Research	Lacks authentication (Rule 901)
7118		"Leadership Takes Many Forms" Professional Sales Material	Lacks authentication (Rule 901)
7119		Sales Training Material	Lacks authentication (Rule 901)
7120		Children's Motrin Marketing Exclusivity Document	Lacks authentication (Rule 901)
7121		Pediatric Product Information	Lacks authentication (Rule 901)
7122		Sales Materials- Year 1 Results	Lacks authentication (Rule 901)
7123		Documents regarding "Temperature Drop" campaign	Lacks authentication (Rule 901)
7124		Documents regarding "Sisters" campaign	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
7125		1996 print advertisements for Children's Motrin	Lacks authentication (Rule 901)
7126		Deposition of Mr. Bass from Langstaff v. McNeil	
7127		Deposition of Peter Bell from Langstaff v. McNeil	
7128		Deposition of Ashley McEvoy from Langstaff v. McNeil	
7129		Deposition of Tony Temple from Langstaff v. McNeil	
7130		Deposition of Ashley McEvoy from Gaines v. McNeil	
7131		Deposition of Tony Temple from Johnson v. Johnson & Johnson	
7132		Deposition Transcripts from Wolfe v. McNeil	
7133		Letter from DDMAC to McNeil	Lacks authentication (Rule 901)
7134		6/19/95 document from FDA clearing Children's Motrin for OTC Marketing	Lacks authentication (Rule 901)
7135		Expert Report and C.V. of James B. Hoyme, M.D.	
7136		Report of MMPI Interpretation of Victor Malatesta, Ph.D.	
7137		Expert Report of William Bruce Jones, M.D.	
7138		Articles referenced by Dr. Jones cited as (Bacur 1987), (Tiling 1971), (Watkins, et al. 1988, 1992), (Andreasen, e al. 1972), (Steiner, et al., 1977), (Counaternache, et al. 1989), (May, et al. 1984), (Noyes, et al., 1971), (Hughes & Cayaffa 1973), (Varney, et al. 1992), (Browne, et al. 1985), (Faber, et al. 1987, (Haber et al. 2005)	
7139		Expert Report and C.V. of Steven Pliskow, M.D., FACOG, FACFE	
7140		Expert Report and C.V. of Robert C. Nelson, Ph.D.	
7141		Documents from Langstaff v. McNeil	
7142		Documents from Esnard v. McNeil	
7143		Documents from Johnson v. McNeil	
7144		Documents from Saw v. McNeil	
7145		Documents from Rhoden v. McNeil	
7146		Documents from Zundel v. McNeil	
7147		Documents from Robinson v. McNeil	

Exh No.	Date	Description	Defendants' Objections
7148		The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective (http://www.fda.gov/Drugs/ResourceForYou/Consumers/ucm133534)	
7149		http://www.fdagov/cder/guidance/index.htm	
7150		Wyeth v. Levine, 129 S. Ct. 1187 (2009)	
7151		Bradford Hill Criteria for assessing and establishing general causation	
7152		21 C.F.R. 201.5	
7153		21 C.F.R. 201.56	
7154		21 C.F.R. 201.80	
7155		21 C.F.R. 201.128	
7156		21 C.F.R. 201.120	
7157		21 C.F.R. 201.115	
7158		21 C.F.R. 201.117	
7159		21 C.F.R. 201.119	
7160		21 C.F.R. 201.120	
7161		21 C.F.R. 201.122	
7162		21 C.F.R. 312.32	
7163		21 C.F.R. 314.80	
7164		21 C.F.R. 314.81	
7165		21 C.F.R. 314.50	
7166		21 C.F.R. 314.55	
7167		21 C.F.R. 314.97-314.98	
7168		21 C.F.R. 314.150	
7169		FDA Review (Judith Jones, 1983)	
7170		FDA-FOI, WHO, CSM- Skin ADEs (1974-1989)	Lacks authentication (Rule 901)
7171		FDA-FOI, WHO, CSM- Skin ADEs (1990-1996)	Lacks authentication (Rule 901)
7172		FDA-FOI WHO databases	Lacks authentication (Rule 901)
7173		McNeil Databases re NSAIDs and SJS/TENS	Lacks authentication (Rule 901)
7174	1994	Ahmad, S.R., et. al.: Analysis and Comparison of Adverse Drug Experience Reporting by Different Reporters to the FDA. Pharmacoepidemiology & DrugSafety, 1994	
7175	2002	Auquir-Dunant A, and the SCAR Study Group, Correlations between clinical patterns and causes of Erythema Multiforme Majus, Stevens-Johnson Syndrome, and Toxic Epidermal Necrolysis. Arch Dermal. 2002; 138:1019-1024	

Exh No.	Date	Description	Defendants' Objections
7176	1985	Begaud B, Evreux JC, Jouglard J, et al. Unexpected or toxic drug reaction assessment (imputation). Actualisation of the method used in France. Therapie 1985; 40: 111-8	
7177	1998	Benefit-Risk Balance for Marketed Drugs: Evaluating Safety Signals. Report of CIOMS Working Group IV. Council of International Organizations of Medical Sciences (CIOMS), Geneva, 1998.	
7178	1994	Benichou C. Adverse drug reactions: a practical guide to diagnosis and management. New York; John Wiley & Sons, 1994	
7179		Benichou C. Imputability of unexpected or toxic drug reactions. In: Benichou C. Adverse drug reactions: a practical guide to diagnosis and management. New York: Wiley & Sons, 1994:271-5	
7180		NO EXHIBIT	
7181	1997	Besag FMC, Dulac O, Alving J, Mullens EL. Long terms safety and efficacy of lamotrigine (Lamactil7) in paediatric patients with epilepsy. Seizure 1997;6:51-56	
7182	1986	Bigby M, Jick S, Jick H, Arndt K. Drug-induced cutaneous reactions. A report from the Boston Collaborative Drug Surveillance program on 154,538 consecutive inpatients, 1975 to 1982. JAMA 1986; 256:3358-63.	
7183	2002	Bright R, Nelson RC. Automated support for pharmacovigilance: a proposed system. Pharmacoepidemiology and Drug Safety 2002; 11:121-125	
7184	1998	Council for International Organizations of Medical Science (CIOMS). Report of CIOMS Working Group IV. Benefit - risk balance for monitored drugs: evaluating safety signals. WHO Geneva 1998	Lacks authentication (Rule 901)
7185	1984	Doll R. Occupational cancer: Problems in interpreting human evidence. Ann Occup Hyg 1984;28:291-305	
7186	1996	Dooley J, Camfield P, Gordon K, Camfield C, Wirrell E, Smith E. Lamotrigine-induced rash in children. Neurology 1996; 46:240-2	

Exh No.	Date	Description	Defendants' Objections
7187	1976	Evans AS. Causation and disease: The Henle-Koch postulates revisited. Yale J Biol Med 1976;49: 175-195	
7188	1982	Finney., DJ., The Detection of Adverse Reactions to Therapeutic Drugs. Stat Med 1982; 1: 153-161.	
7189	1971	Finney, DJ., Statistical Aspects of Monitoring for Dangers in Drug Therapy. Methods Information Med 1971; 10:1-8.	
7190	1999	Guberman AH, Besag FMC, Brodie MJ, Dooley JM et.al. Lamotrigine-associated rash: risk/benefit considerations in adults and children. Epilepsia 1999; 40(7):985-991	
7191	1987	Guillaume JC, Roujeau JC, Recuz J, Penso D, Touraine R. The culprit drugs in 87 cases of toxic epidermal Necrolysis (Lyell's Syndrome) Arch Dermatol 1987;123:1166-70	
7192	2005	Guzelelian PS et al. Evidence-based toxicology: a comprehensive framework for causation. Hum Exp Toxicol 2005;24: 161-201	
7193	1979	Hackney, JD, Linn WS. Koch's postulates updated: A potentially useful application to laboratory research and policy analyses in environmental toxicology. Am Rev Respir Disease 1979; 119:849-852	
7194	1983	Hanley JA, Lippman-Hand A: "If nothing goes wrong is everything all right? Interpreting zero numerators". Journal of the American Medical Association. 1983;249(13): 1743-1745,.	
7195	1998	Hartzema, AG, Porta, MS. Tilson HH. Pharmacoepidemiology, an Introduction. 3rd edition. Harvey Whitney books Company, Cincinnati, OH. 1998	
7196	1965	Hill AB. The environment and disease: Association or causation? Proceedings of the Royal Society of Medicine. 1965;58:295-300.	
7197	1987	Heimbach DM, Engav LH, Marvin JA et.al., Toxic Epidermal Necrolysis. A step forward in treatment. JAMA 1987;257:2171-5.	
7198		Inman WHW. "Post-Marketing Surveillance in the General Population:United Kingdom," in Inman WHW, ed. Monitoring for Drug Safety, JB Lippincott Co., Philadelphia, 1980.	

Exh No.	Date	Description	Defendants' Objections
7199		Inman, WHW., Postmarketing Surveillance of Adverse Reactions in General Practice. I: Search for the New Methods. British Medical Journal 282: 1131. II: Prescription-event Monitoring at the University of Southampton. British Medical Journal 282:1216.	
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7201	2000	Jones, JK., "Determining Causation from Case Reports." In Strom, ed., Pharmacoepidemiology Third Edition., John Wiley & Sons, L TD., 2000; 526-538.	
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7204	2001	Jones, JK., "The Role of Data Mining Technology in the Identification of Signals of Possible Adverse Drug Reactions: Value and Limitations." Current Therapeutic Research 2001; 62: 664-672.	
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7207	1981	Naranjo C, Busto U, Sellers EM. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981; 30: 239-45	
7208	2002	Nelson RC, et al, Good Pharmacovigilance Practices, Technology Enabled, Drug Safety 2002; 25(6): 407-414	

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7209	1998	Nelson, R.C., Pederson, D., D'Souza, T.: U.S. FDA AERS Project. Book chapter in Electronic Communication Technologies, Mervyn Mitchard, ed., InterPharm Press, 1998.	
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7211	2007	Pichler WJ. Drug Hypersensitivity Reactions: Classification and Relationship to T-Cell Activation. In Pichler WJ (ed.): Drug Hypersensitivity. Basel, Karger, 2007, pp.168-189	
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7218	2005	Sturenboom M, Nicolosi A, Cantraruutti L, et. al. Incidence of Mucocutaneous reactions in children treated with Niflumic Acid, other Non-steroidal anti-inflammatory drugs, or Non-opioid analgesics. Pediatrics 2005; 116;e26-e33.	
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Exh No.	Date	Description	Defendants' Objections
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Exh No.	Date	Description	Defendants' Objections
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Exh No.	Date	Description	Defendants' Objections
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Exh No.	Date	Description	Defendants' Objections
7275	1982	Addition to FPL for Motrin/Advil dated 1982	Lacks authentication (Rule 901)
7276	1988	Addition to FPL for Pedatric Motrin/Advil dated 1988	Lacks authentication (Rule 901)
7277	1994	Addition to FPL for Pediatric Motrin dated 1994	Lacks authentication (Rule 901)
7278	1995	BUFS (Lesko, 1995)	
7279		SCAR	Lacks authentication (Rule 901)
7280		EuroSCAR	Lacks authentication (Rule 901)
7281		Expert Report and C.V. of Manuela G. Neuman M.Sc., Ph.D., FCACC	
7282		Liver Toxicity Assay Results	Lacks authentication (Rule 901)
7283	2008	Neuman, M., et al., European Journal of Dermatology, "Cytokines-Chemokines and Hypersensitivity Syndrome Reactions to Ibuprofen", 18(2):269-270 (2008).	
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7290	2000	Neuman, M., et al., Clinical Biochem, "A Novel Lymphocyte Toxicity Assay to Assess Drug Hypersensitivity Syndromes," Vol. 33 No. 7, pp. 517-524 (2000)	

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7294	2000	Neuman, M., et al., Hepatology, "Gender Differences in Serum Cytokines in Patients with Hypersensitivity Reactions to Sulfonamide," Vol. 32, No. 4, Abs. 1365, p. 501A (2000)	
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7296	2003	Neuman, M., et al., Gastroenterology, "Signaling for Hypersensitivity Syndrome Reactions," 124(4) suppl. 1, S 883, A 720 (2003)	
7297	2003	Neuman, M., et al., Ther. Drug Monitoring, "Diagnostic and Monitoring of Toxic Epidermal Necrolysis," 25,4, abs. 204, p. 537 (2003)	
7298	2003	Pichler, WJ, Ann. Intern. Med., "Delayed Drug Hypersensitivity Reactions," Vol. 139 pp. 683-693 (2003)	
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7301	2001	Zanni, et al., Clin. Exp. Allergy, "T Cell Involvement in Cutaneous Drug Eruptions," Vol. 31, pp. 1398-1408 (2001)	
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7304	2006	Beeler, A, et al., J. Allergy Clin. Immunol., "Long-Lasting Reactivity and High Frequency of Drug-Specific T Cells After Severe Systemic Drug Hypersensitivity Reaction," Vol. 117, pp. 455-462 (2006)	
7305	1998	Spielberg, S.P., J. Pharmacol. Exp. Ther., "Acetaminophen Toxicity in Human Lymphocytes In Vitro," Vol. 213, pp. 395-398 (1998)	
7306	1981	Spielberg, S.P., et al., N. Engl. J. Med., "Predisposition of Phenytoin Hepatotoxicity Assessed In Vitro," Vol. 305, pp. 722-727 (1981)	
7307	1991	Spielberg, S.P., et al., Ann. Intern. Med., "In Vitro Assessment of Hypersensitivity Reactions to Sorbinil," Vol. 114, pp. 720-724 (1991)	
7308	1998	Shear, N.H., et al., J. Clin. Invest., "Anticonvulsant Hypersensitivity Syndrome: In Vitro Assessment of Risk," Vol. 82, pp. 1826-1832 (1988)	
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7311		Kearns, Gregory, et al., J. Pediatrics, "Serum Sickness-Like Reactions to Cefaclor: Role of Hepatic Metabolism and Individual Susceptibility," Vol. 125, No. 5, pp. 805-811 (1994)	
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7314	1998	Gharaibeh, MN, et al, "Adverse Drug Reactions: Review," Drug Information Journal, Vol. 32, pp. 323-338 (1998)	
7315	2002	Lee, CR, et al., Pharmacogenetics, "Cytochrome P450 2C9 (CYP2C9) Polymorphisms: A Comprehensive Review of the In-Vitro and Human Data," Vo. 12, No., 3, pp. 251-263 (2002)	
7316	2002	Kircheiner, J., et al., Clin. Pharmacol. Ther., "Impact of CYP2C9 Amino Acid Polymorphisms on Glyburide Kinetics and on the Insulin and Glucose Response in Healthy Volunteers," Vol. 71, pp. 286-296 (2002)	
7317	2002	Miners, J., Pharmacogenetics, "CYP2C9 Polymorphysm: Impact on Tolbutamide Pharmacokinetics and Response," Vol. 12, pp. 91-92 (2002)	
7318	1988	Nouws, JF, et al., Am. J. Vet. Res., "Pharmacokinetics, Metabolsm and Renal Clearance of Sulfadiazine, Sulfamerazine and Sulfamethazine and of their N4-Acetyl and Hydroxy Metabolites in Calves and Cows," Vol. 49, pp. 1059-1065 (1988)	
7319	1998	Miners, J.O., et al., Br. J. Clin. Pharmacol., "Cytochrome P4502C9: An Enzyme of Major Importance in Human Drug Metabolism," Vol. 45, pp. 525-538 (1998)	
7320	1993	Leeman, TD, et al., Drugs Experimental Clin. Res., "A major rolefor cytochrome P450 TB (CYP2C subfamily) in the actions of non-steroidal anti-inflammatory drugs," Vol. XIX, No. 5, pp. 189-195 (1993)	
7321		NO EXHIBIT	
7322	2005	Winter, H., et al., Drug Metabolism and Disposition, "Identification of Cytochrome P450 and Aralamine – Acetyltransferase Isoforms Involved in Sulfadiazine Metabolism," Vo. 33, No. 7, pp. 969-976 (2005).	

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7323	2003	Shapiro, L. et al., Drug Safety, "Safety of Celecoxib in Individuals Allergic to Sulfonamide: A Pilot Study," Vol. 26, No. 3 pp. 187-195 (2003)	
7324	1996	Shapiro, L., et al., Seminars in Cutaneous Medicine and Surgery, "Mechanisms of Drug Reactions: The Metabolic Track," Vol. 15, No. 4 pp. 217-227 (1996)	
7325		Mossman, T., J. Immunol. Methods, "Rapid Colorimetric Assay for Cellular Growth and Survivals: Application to Proliferation and Cytotoxicity Assays" Vol. 65, pp.55-63 (1983)	
7326	1986	Gerlier, D., et al., J. Immunol. Methods, "Use of MTT colorimetric assay to measure cell activation" Vol. 94, pp. 57-63 (1986)	
7327	1986	Cole, S.P.C., Cancer Chemother. Pharmacol., "Rapid chemosensitivity testing of human lung tumor cells using the MTT assay," Vol.17, p. 259 (1986)	
7328	1990	Ferrari, M., et al., J. Immunol. Methods, "MTT Colormetric Assay for Testing Macrophage Cytotoxic Activity in Vitro," Vol. 131, No. 2, pp. 165-172 (1990)	
7329	1992	Loveland, BE et al., Biochemistry International, "Validation of the MTT dye assay for enumeration of cells in proliferative and antiproliferative assays," Vol. 27, pp. 501-510 (1992)	
7330	1987	Nebert, DW, et al., Ann. Rev. Biochem., "P450 Genes: Structure, Evolution and Regulation," Vol. 56, pp. 945-993 (1987)	
7331	1996	Shear, et al., Textbook on Cutaneous Medicine and Surgery (1996)	
7332	VARIOUS	Fitzpatrick's Dermatology (2003, 1999 and 1996)	
7333	2005	Journal of Annals of Allergy, Asthma & Immunology (2005)	

Exh No.	Date	Description	Defendants' Objections
7334	Various	Other medical literature relied on by Manuela Neuman in her report, cited as (Gruchalla, 2001), (Svensson 2000),(Desai and Johnston 2006), (Hall 1986), (Oker 2000), (Wood 2006), (Downie 1993), (Seifert 2000), (Krivoy 2006), (Jurima-Romet 1994), (Chung, 2007), (Beeler 2006), (Vassalli, 1992), (Luster, 1999), (Ertel, 1991), (Wanner 1998), (Mascagni 2000), (Walker 1997), (Turner 1984), (Shear 1990), (Neuman 2000), (Tigka 2005), (Shapiro, 2003), (Wolkenstein 1995), (Friedman 1994), (Farrell 1998), (Gerson 1983), (Neuman 1999), (Banihani 2010), (Banihani 2009), (Neuman and Winkler Rom J. of Hepatology 2009), (Biochemical Pharmacology, Vol. 54, pp. 33-41(1997)),	
7335		Expert Report and C.V. of Eric Pierce, M.D., Ph.D.	
7336		Expert Report and C.V. of Philip Rosenthal, M.D.	
7337		Kiley Wolfe's Medical Records	
7338		Depositions from Wolfe v. McNeil	
7339		United Network for Organ Sharing Website	Lacks authentication (Rule 901)
7340		Medical Literature in Rosenthal C.V. regarding liver retransplantation.	
7341		Expert Report and C.V. of Roger E. Salisbury, M.D.	
7342		FDA Regulations Relative to Labeling of Prescription and Over-the-Counter Products	Lacks authentication (Rule 901)
7343		Labeling for Motrin and Children's Motrin (U.S. and other countries)	Lacks authentication (Rule 901)
7344		Adverse Drug Experience Reports of Serious Skin Reactions Received and filed by McNeil and/or Johnson and Johnson	Lacks authentication (Rule 901)
7345		Deposition Transcripts from Langstaff v. McNeil	
7346		Deposition Transcripts from Lofton v. McNeil	
7347		Deposition Transcripts from Johnson v. McNeil	
7348		McNeil's Spontaneous Reports for NDAs 19-842 (Rx Children's Motrin)	Lacks authentication (Rule 901)
7349		McNeil's Spontaneous Reports for NDAs 20-516 (OTC Children's Motrin)	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
7350		ADEs for other single ingredient products (1978-2002)	Lacks authentication (Rule 901)
7351		Spontaneous Reports from WHO data base between 1980-2002 for mucotaneous reactions associated with ibuprofen products	Lacks authentication (Rule 901)
7352		FDA Spontaneous Reports from 1969-2003 for single ingredient ibuprofen products	Lacks authentication (Rule 901)
7353		BUFS documents	Lacks authentication (Rule 901)
7354		CMS ADEs	Lacks authentication (Rule 901)
7355		MCA Adverse Event Reports	Lacks authentication (Rule 901)
7356		Domestic and Foreign Labels and Warnings for Pediaprofen	Lacks authentication (Rule 901)
7357		Domestic and Foreign Labels and Warnings for Children's Motrin	Lacks authentication (Rule 901)
7358		Canadian HPB NSAID warnings for SJS/TEN	Lacks authentication (Rule 901)
7359		Notebook of Spontaneous Reports from McNeil for Cases of EMS, SJS and TEN	Lacks authentication (Rule 901)
7360		Promotional and Advertising Materials for Pediaprofen	Lacks authentication (Rule 901)
7361		Promotional and Advertising Materials for Children's Motrin	Lacks authentication (Rule 901)
7362		American Pharmaceutical Association Product Bulletin on Children's Motrin	Lacks authentication (Rule 901)
7363		Comprehensive Review of the Safety of Ibuprofen in Pediatric Patients	Lacks authentication (Rule 901)
7364		DDMAC letters to McNeil Regarding Children's Motrin	Lacks authentication (Rule 901)
7365	Aug-84	Weisman R, Howland M, Goldfrank L. Ibuprofen: An analysis of safety and efficacy. August 1984.	
7366		Citizen's Petition Against Advil Rx to OTC Switch	
7367		Judith Jones' Report to FDA Advisory Committee Regarding Skin Reactions	Lacks authentication (Rule 901)
7368		American Home Products Presentation Materials on Safety and Efficacy of Ibuprofen	Lacks authentication (Rule 901)
7369		FDC Reports on Motrin and Ibuprofen Products	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
7370		Pre-NDA meeting notes for Pediaprofen and Rx. to OTC Switch for Children's Motrin	Lacks authentication (Rule 901)
7371		Medical Officer Reviews of NDA 19-842	Lacks authentication (Rule 901)
7372		Medical Officer Reviews of NDA 20-516	Lacks authentication (Rule 901)
7373		Boston University Fever Study consent forms	Lacks authentication (Rule 901)
7374		BUFS Advisory Committee reports	
7375		Preliminary Statistical Data	Lacks authentication (Rule 901)
7376		Protocols and Data Collection Policies	Lacks authentication (Rule 901)
7377		Presentation materials to NDAC	Lacks authentication (Rule 901)
7378		McNeil Safety policies and procedures for adverse experience reporting	Lacks authentication (Rule 901)
7379		Annual and Periodic Reports for NDAs 19-842 and 20-516	Lacks authentication (Rule 901)
7380		Professional and OTC labeling for various pediatric Adult and Motrin products	Lacks authentication (Rule 901)
7381		PILs for Patient Safety Information	Lacks authentication (Rule 901)
7382		Foreign Labeling for Advil	Lacks authentication (Rule 901)
7383		Correspondence between Wyeth and FDA regarding warnings about SJS in OTC label	Lacks authentication (Rule 901)
7384	5-May	Wyeth's filing of serious skin reactions in May 2005	Lacks authentication (Rule 901)
7385		NDA 17-463 Clinical Trial Data	Lacks authentication (Rule 901)
7386		NDA 17-463 Case Reports	Lacks authentication (Rule 901)
7387		NDA 17-463 ADEs	Lacks authentication (Rule 901)
7378		NDA 17-463 Supplemental Applications and clinical trial data and ADEs	Lacks authentication (Rule 901)
7379		Quarterly Updates to NDA 17-463	Lacks authentication (Rule 901)
7380		Biannual Reports to NDA 17-463	Lacks authentication (Rule 901)
7381		Postmarketing Adverse Experiences from NDA 17-463	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
7382		Progress Reports for Clinical Trial Data for NDA 17-463	Lacks authentication (Rule 901)
7383		Annual ADE Reports for 17-463	Lacks authentication (Rule 901)
7384		Periodic ADE Reports for 17-463	Lacks authentication (Rule 901)
7385		NDA 19-012 Clinical Trial Data	Lacks authentication (Rule 901)
7386		NDA 19-012 Case Reports	Lacks authentication (Rule 901)
7387		NDA 19-012 ADEs	Lacks authentication (Rule 901)
7388		NDA 19-012 Supplemental Application and clinical trial data and ADEs	Lacks authentication (Rule 901)
7389		Motrin Migraine Quarterly Updates to NDA 19-012	Lacks authentication (Rule 901)
7390		Motrin Migraine Bi-Annual Reports to NDA 19-012	Lacks authentication (Rule 901)
7391		Postmarketing Adverse Experience from NDA 19-012	Lacks authentication (Rule 901)
7392		Progress Reports for Clinical Trial Data for NDA 19-012	Lacks authentication (Rule 901)
7393		Annual ADE Reports NDA 19-012	Lacks authentication (Rule 901)
7394		Annual ADE Reports for 19-012	Lacks authentication (Rule 901)
7395		Periodic ADE Reports for 19-012	Lacks authentication (Rule 901)
7396		SNDA's and CBE changes for Motrin IB, Nuprin or Haltran products	Lacks authentication (Rule 901)
7397		Submissions in Response to FDA requests to add SJS/TEN warnings to FDA	Lacks authentication (Rule 901)
7398		McNeil Internal documents Safety Policies and Procedures for Adverse Event collection and Reporting ADEs	Lacks authentication (Rule 901)
7399		CRS data entry retrieval	Lacks authentication (Rule 901)
7400		Safety Information Exchange between McNeil/J&J and Pharmacia & Upjohn (PNU)	Lacks authentication (Rule 901)
7401		Medical Literature Identification and Reporting	Lacks authentication (Rule 901)
7402		Foreign Reporting between PNU and McNeil	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
7403		McNeil and J&J Safety Policies	Lacks authentication (Rule 901)
7404		Spontaneous Reports of Serious Skin Reactions and Source Documents	Lacks authentication (Rule 901)
7405		European Pharmacovigilance Regulations and Practices	Lacks authentication (Rule 901)
7406		Comparable Safety of Antipyretics and Analgesis	Lacks authentication (Rule 901)
7407		WHO Rejection of Ibuprofen to Essential List of Medicines	Lacks authentication (Rule 901)
7408		Ibuprofen Industry Association Materials	Lacks authentication (Rule 901)
7409		EMA Revision to NSAID labeling	Lacks authentication (Rule 901)
7410		FDA Memorandum on NSAID labeling	Lacks authentication (Rule 901)
7411		Provigil Memorandum by FDA and FDA Arthritis Committee	Lacks authentication (Rule 901)
7412		TMF for 200mg Ibuprofen	Lacks authentication (Rule 901)
7413		21 CFR 201.56	
7415		21 CFR 201.57	
7416		21 CFR 201.66	
7417		21 CFR 202.1	
7418		21 CFR 312.64	
7419		21 CFR 314.26	
7420		21 CFR 314.50	
7420		21 CFR 314.70	
7421		21 CFR 314.80	
7422		21 CFR 314.81	
7423		21 C.F.R. 369.1	
7424		21 C.F.R. 369.10	
7425	2007	Nelson's Textbook on Pediatrics, 18th Edition, Chapter 653, Vesiculobullous Disorders, pp. 2685-2693 (2007)	

Exh No.	Date	Description	Defendants' Objections
7426	1995	Roujeau, JC, et al., Intensive Care Medicine, "Pulmonary Complications in Toxic Epidermal Necrolysis: A Prospective Clinical Study," Vol. 23, No. 12, pp. 1237-1244 (1997) Assier H, et al., Arch Dermatol., "Erythema Multiforme With Mucous Membrane Involvement and Stevens-Johnson Syndrome are Clinically Different Disorders with Distinct Causes," Vol. 131, pp. 539-543 (1995)	
7427	2000	Additional literature reviewed by Dr. Salisbury, cited as (Ferrell 2001), (Descamps, et al. 2001), (Svennson 2000)	
7428		Expert Report and C.V. of George M. Samaras, Ph.D., DSC, PE, CPE, CQE	
7429		ISO 14971 International Consensus Standard on Risk Management	Lacks authentication (Rule 901)
7530		Woodson, WE, Tillman, B and Tillman P., Human Factors Design Handbook, 2nd Ed., McGraw-Hill 1992	
7531		MC063711-MC06316	
7532		http://www.medsafe.govt.nz/Profs/PUArticles/sca rs.htm Printouts	Lacks authentication (Rule 901)
7533	1980	Sternlieb, P. & Robinson, RM, Ann. Int. Med., "Letter to the Editor," Vol. 92 p. 570 (1980)	
7534	1982	Hindson, C., et al., Br. Med. J., "Side effects of benoxaprofen," vol. 284, pp. 1368-1369 (1982)	
7535		GISED, Dermatology, "Cutaneous Reactions to Analgesic-Antipyretics and Nonsteroidal Anti-Inflammatory Drugs," Vol, 186, pp. 164-169	
7536		Laughery KR & Wogalter MS, Chapter 36: Warnings and Risk Perception in Handbook of Human Factors and Ergonomics, 2nd Edition, G. Salvendy (Ed.) Wiley-Interscience (1997)	
7537		http://www.osha.gov/dsg/hazcom/hc2inf2.html Printouts	Lacks authentication (Rule 901)
7538		Expert Report and C.V. of Randall Tackett, Ph.D.	
7539	2/24/2005	February 24, 2005 Correspondence from Dr. Salisbury to the FDA	
7540		Spontaneous Reports from WHO data base between 1980-2005 for mucotaneous reactions associated with ibuprofen products	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
7541		Annual and Periodic Reports for NDAs 19-842, 20-516, 19-899, 19-012, 20-601, 20-602, 20-603, 21-128	Lacks authentication (Rule 901)
7542		McNeil Product Safety Reviews	Lacks authentication (Rule 901)
7543		Editorial, "The Time to Act on Drug Safety", New England Journal of Medicine (May 20, 1998)	
7544		Lazarou, J, et al., JAMA, "Incidence of Adverse Drug Reactions in Hospitalized Patients: a Meta-Analysis of Prospective Studies," Vol. 279, pp. 1200-1205 (1998)	
7545		Furberg, CD, et al., "The FDA and Drug Safety: A Proposal for Sweeping Changes, Arch Intern Med. Vol. 166, pp. 1938-1942	
7546	2004	Furberg, CD, et al., JAMA, "Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions," Vol. 292, pp. 2622-2631 (2004)	
7547	2004	Strom, BL, JAMA, "Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions: A Counterpoint," Vol. 292, pp. 2643-2646 (2004)	
7548	2009	U.S. GAO report to Congress, "High Risk Series, an Update." (2009)	Lacks authentication (Rule 901)
7549	2006	U.S. GAO report, "Drug Safety: Improvement Needed in FDA's Post-market Decisionmaking and Oversight Process" (2006)	Lacks authentication (Rule 901)
7550	2007	National Academies, Institute of Medicine, "The Future of Drug Safety: Promoting and Protecting the Health of the Public," (2007)	Lacks authentication (Rule 901)
7551	Nov-07	FDA Science and Mission at Risk, Report of Subcommittee on Science and Technology (November 2007)	Lacks authentication (Rule 901)
7552	2000	Strom, BL, Pharmacoepidemiology, 3rd Ed., 2000, pp. 151-174	
7553	2001	Iaoniddis, JP, et al., JAMA, "Completeness of Safety Reporting in Randomized Trials: An Evaluation of 7 Medical Areas," pp. 437-443 (2001)	

Exh No.	Date	Description	Defendants' Objections
7554	3/23/2006	Memorandum, FDA Medical Officer Review of Provigil, February 27, 2006 and Psychopharmacologic Advisory Committee (PDAC) March 23, 2006	
7555	2002	Lasser, KE, et al., JAMA, "Timing of New Black Box Warnings and Withdrawals for Prescription Medications," Vol. 287, pp. 2215-2220 (2002)	
7556		Bennett, CL, et al., JAMA, "Radar Project," pp. 2131-2140	
7557	1996	Goldman, S, MEDWATCH, "The Clinical Impact of Adverse Event Reporting," pp. 1-12 (1996)	
7558	2002	Omar, M.A., et al., Annals of Pharmacotherapy, "FDA Adverse Event Reports on Statin-Associated Rhabdomyolysis," pp. 288-295 (2002)	
7559		NO EXHIBIT	
7560		Scott, H.D., et al., JAMA, "Physician Reporting of Adverse Drug Reactions. Results of Rhode Island Adverse Drug Reactions Reporting Project," Vol. 263, pp. 1785-1788 (1990)	
7561	2004	Shear, N., Drug Safety, "The Evaluation of the Extent of Under-Reporting: The Case of Toxic Epidermal Necrolysis," Vol. 27, pp. 477-487 (2004)	
7562	2005	Abraham, A, Social Science and Medicine, "A Comparative Analysis of Drug Safety Withdrawals in the UK and the US (1971-1992): Implications for Current Regulatory Thinking and Policy," Vol. 61, 881-892 (2005)	
7563	2007	Isawi, et al., J. Cataract Refract Surg., "Corneal Melting and Perforation in Stevens Johnson Syndrome Following Topical Bromfenac Use," Vol. 33, No. 9, pp. 1644-1646 (2007)	
7564	2009	Cho, Clinical Ophthalmology, "Management of Ocular Inflammation and Pain Following Cataract Surgery: Focus on Bromfenanc Ophthalmic Solution," Vol. 3, pp. 199-210 (2009)	

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7565	2003	Grillo, et al., Drug Metabolism and Disposition, "Identification of Zomepirac-S-Acyl-Glutathione in Vitro in Incubations with Rat Hepatocytes and in Vivo in Rat Rat Bile," Vol. 31, No. 11, pp. 1429-1436 (2003)	
7566	1982	Hindson, BMJ, "Side Effects of Benoxaprofen," Vol. 284, pp. 1368-1369 (1982)	
7567	1999	Waller, PC, et al, Pharmaceoeepidemiology and Drug Safety, "Responding to Drug Safety Issues," Vol. 8, pp. 535-552 (1999)	
7568	2007	Hochberg, AM, et al., Drug Information Journal, "Using Data Mining to Predict Safety Actions from FDA Adverse Event Reporting System Data," Vol. 41, pp. 633-643 (2007)	
7569	2004	Nassif, et al., J. Invest Dermatology, "Evaluation of the Potential Role of Cytokines in Toxic Epidermal Necrolysis," Vol. 123, pp. 850-855 (2004)	
7570	2005	Roujeau, JC, et al., Toxicology, "Clinical Heterogeneity of Drug Hypersensitivity," Vol. 209 pp. 123-129 (2005)	
7571	2006	Roujeau, JC, et al., Am J. Clin. Dermatol., "Differential Diagnosis of Severe Cutaneous Drug Eruptions," Vol. 4, No. 8, pp. 561-572 (2006)	
7572	1998	Wolkenstein PR, et al., Clin. Dermatol., "Drug-Induced Toxic Epidermal Necrolysis," Vol. 16, pp. 399-409 (1998)	
7573	1991	Rudy, et al., J. Pharmacol. Exp. Ther., "Stereoselective Metabolism of Ibuprofen in Humans: Administration of R-, S- and Racemic Ibuprofen," Vol. 259, pp. 1133-1139 (1991)	
7574	1997	Hamman MA, et al., Biochem Pharmacol, "Regioselective and stereoselective metabolism of ibuprofen by human cytochrome P450 2C." Vol. 51, No. 1, pp. 33-41(1997)	
7575	1994	Other Articles Cited by Tackett referenced as (Klein 1993) (Klein, et al. 1994) (Kulich, et al. 1994) (Descamps, et al. 2001), (Svennson, 2000), (Sasaki 1970), (Gasparetto 1974)	
7576	1992	Saskatchewan Study on NSAIDs Published in 1992	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
7577	2003	Saskatchewan Study on NSAIDs Published in 2003	Lacks authentication (Rule 901)
7578	1993	Carson et al, Study Published in 1993	Lacks authentication (Rule 901)
7579	1994	U.K. Vamp Study Published in 1994	Lacks authentication (Rule 901)
7580	1995	Lanza et al Study Published in 1995	Lacks authentication (Rule 901)
7581		NSAID New Medication Guide	Lacks authentication (Rule 901)
7582		FDA Guidance "Changes to an Approved NDA or ANDA (November 1999) and Revision 1 to this Guidance	
7583		69 F.R. 18728	
7584	2001	FDA Guidance for Industry-Labeling OTC Human Drug Products Updating Labeling in ANDAS (February 2001)	
7585		FDA Medical Officer's Review Memo and Transcript of Advisory Committee on Provigil	Lacks authentication (Rule 901)
7586		Expert Report and C.V. of Talal Chatila, M.D., M.Sc.	
7587		Expert Report and C.V. of Jonathan Walker, M.D.	
7588		Expert Report of Randall Tackett, Ph. D. (Lofton v McNeil and J & J)	
7589		Randall L. Tackett, Ph.D. Curriculum Vitae	
7590		Citizen Petition to Request Risk Assessment of SJS	
7591		and Ten dated Feb 15, 2005	
7592		FDA Question and Answers on Regulatory Actions	
7593		for the COX-2 Selective and Non-Selective	
7594		Non-Steroidal Anti-inflammatory drugs (NSAIDs)	
7595		FDA Food & Drug Administration - -FDA News - - "FDA Announces	
7596		Series of Changes to the Class of Marketed Non-Steroidal Antiinflammatory	
7597		Drugs (NSAIDs) dated April 7, 2005	
7598		Department of Health & Human Services NDA Labeling Revision	
7599	22-Jun-06	FDA Response letter to Dr. Roger Salisbury Docket No. 2005P-0072/CPI	

Exh No.	Date	Description	Defendants' Objections
7600		Moore, Thomas J, et. ai, "Time to Act on Drug Safety", JAMA, Vol. 279, No. 19, pages 1571-1573, (1998)	
7601		Lazarous, Jason, et. ai, "Incidence of Adverse Drug Reactions in	
7602		Hospitalized Patients", JAMA, Vol. 279 No. 15, pages 1200 - 1205,	
7603		Furberg, Curt D., et. al., "The FDA and Drug Safety: A Proposal for	
7604		Sweeping Changes", Archives of Internal Medicine, Alliance for Human	
7605		Research Protection, (2006)	
7606		Title 21 - Food and Drugs, Chapter 1 - Food and Drug Administration Department of Health and Human Services, SubChapter D - Drugs for Human Use, Part 314	
7607	2001	Ioannidis, John P. M.D., et al., "Completeness of Safety Reporting in Randomized Trials", JAMA, Vol. 285, No.4, pages 437 - 443, (2001)	
7608	2002	Lasser, M.D. Karen E., et al., "Timing of New Black Box Warnings and Withdrawals for Prescription Medications", JAMA, Vol. 287, No. 17, pages 2215 - 2220, (2002)	
7609	2005	Bennett, M.D., Charles. L., et. al., "The Research on Adverse Drug Events and Reports (RADAR) Project", JAMA, Vol. 293, No. 17, pages 2131 - 2140, Letters 1206 - 1207, (2005)	
7610	2004	Psaty, M.D., Bruce M., et. al., "Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions", JAMA, Vol. 292, No. 21, pages 2622 - 2646, (2004)	
7611	2004	Strom, M.D. Brian L., "Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions", JAMA, Vol. 292, No. 21, pages 2643 - 2646, (2004)	
7612	2002	Omar, M A, et al., FDA adverse event reports on statin-associated rhabdomyolysis, The Annals of Pharmacotherapy, Vol. 36, No.2, pages 288-295, (2002)	

Exh No.	Date	Description	Defendants' Objections
7613	1990	Scott, H. D., et al., "Physician reporting of adverse drug reactions. Results of the Rhode Island Adverse Drug Reaction Reporting Project", JAMA, Vol. 263, No. 13, (1990)	
7614	1999	Brewer, M.D., Timothy, et al., "Postmarketing Surveillance and Adverse Drug Reactions", JAMA, Vol. 281, No.9, pages 281 :824-829, (1999)	
7615	2004	Mittrmann, Nicole, et al., "Evaluation of the Extent of Under-Reporting of Serious Adverse Drug Reactions", Drug Safety, 27 (7), 477 -487, (2004)	
7616	2003	Title 21 - Food and Drugs Chapter 1 - Food and Drug Administration, Department of Health and Human Services, SubChapter D - Drugs for Human Use, Part 314.80, pages 121-127, (2003)	
7617	12/24/1992	57 Federal Register 61437, FDA Guideline for Postmarketing Reporting of Adverse Drug Experiences, Docket No. 85D-0249, December 24, 1992	
7618	Aug-97	FDA Guidance For Industry: Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biologic Products: Clarification of What to Report, August 1997	
7619	2001	FDA Guidance For Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines, March 2001	
7620	1989	Stern, M.D., Robert S., et al., "Usefulness of case report literature in determining drugs responsible for toxic epidermal necrolysis", J Am Acad Dermatol, 21:317-22, (1989)	
7621		McNeil's Failure to File/Report Scientific Literature in NDAs and Postmarketing reports for Motrin Products;	Lacks authentication (Rule 901)
7622		Failure to Report SJS cases to Final BUFS Study Report, FDA Medical Officer, and U.S. Non-Prescription Drug Advisory Committee (NDAC)	Lacks authentication (Rule 901)
7623	1/11/1984	McNeil Memorandum RE: IBUPROFEN NDA PROJECT, dated January 11, 1984, MC064778	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
7624	6/18/1984	McNeil PETITION FOR RECONSIDERATION NDA 19-012 & NDA 18-989 dated June 18, 1984	Lacks authentication (Rule 901)
7625	6/18/1984	McNeil PETITION FOR RECONSIDERATION NDA 19-012 & NDA 19-989 dated June 18, 1984 MC067238 & FDC Reports 46(13): T&C-I (March 26) 1984, Trade & Govt. Memos OTC Ibuprofen Labeling based on Rx Package insert information	Lacks authentication (Rule 901)
7626	5/31/1984	McNeil Memorandum to Robert Temple, M.D., RE: Ibuprofen - Summary Basis of Approval, dated May 31, 1984	Lacks authentication (Rule 901)
7627	8/12/1983	Petition for Reconsideration by McNeil Risk of Death higher for Ibuprofen Silberstein, M.D., Barbara H. Korberly, Pharm D. dated August 12, 1983	Lacks authentication (Rule 901)
7628	5/23/1985	McNeil Memorandum. Subject: National Kidney Foundation dated May 23, 1985	Lacks authentication (Rule 901)
7629	9/14/1983	McNeil Memorandum Subject: Arthritis Advisory Committee Meeting Handouts, dated September 14, 1983	Lacks authentication (Rule 901)
7630	9/12/1984	Bellevue Hospital Center Letter to Anthony R. Temple, best updating on ibuprofen from Lewis Goldfrank, dated September 12, 1984	Lacks authentication (Rule 901)
7631		Ibuprofen Review prepared for: David E. Collins by Marsha M.	
7632	3/31/1988	McNeil Letter to FDA regarding New Drug Application Ibuprofen Pediatric Suspension 80mg I 5ml, dated March 31, 1988	
7633		NDA 19-842 Summary Basis of Approval Ibuprofen Pediatric Suspension, 80mg I 5ml New Drug Application, Other Studies and Information, MC06A 000908	
7634		Graph of SRS 1980 Through 1989 17 years or younger, Motrin, Advil, Rufen, Ibuprofen, Nuprin, McNeil Letter Subject: Minutes of Industry Meeting with FDA Post Marketing	
7635	1/29/1990	Surveillance Program - Ibuprofen suspension, dated January 29, 1990	Lacks authentication (Rule 901)
7636	1996	Mitchell, Allen A., et al., "When a Randomised Controlled Trial is Needed to Assess Drug Safety", Drug Safety, 13(1): 125-24, (1996)	

Exh No.	Date	Description	Defendants' Objections
7637	11/2/1993	BUFS - Draft Final Report, dated November 2, 1993	
7638	6/11/1992	NDA 19-842 Pedia-Profen Ibuprofen Suspension Request for FDA Meeting dated 6/11/92, Regulatory Copy	
7639	12/22/1993	Medical Officer Review, NDA 20-516 (Supplement to NDA 19-842), dated December 22, 1993, pages 1 -29	
7640		BUFS Total cases-hospitalized with cutaneous and mucocutaneous	Lacks authentication (Rule 901)
7641		NO EXHIBIT	
7642		Frequency of SJS Docket Number 2005P-0072/CP1 page 3	Lacks authentication (Rule 901)
7643		Presentation to the Arthritis and Non-Prescription Drugs Advisory Committees on the switch of Children's Motrin Ibuprofen Suspension from Prescription to nonprescription status, pages 1 - 269	Lacks authentication (Rule 901)
7644		Presentation to the Arthritis and Non-Prescription Drugs Advisory Committees on the switch of Children's Motrin Ibuprofen Suspension from Prescription to nonprescription status, pages 270	Lacks authentication (Rule 901)
7645		FD-356H New Drug Application for Coated Compressed Tablets Motrin (ibu, U-18, 53), Vol 1.1, Part 1 & 2	Lacks authentication (Rule 901)
7646		Department of Health, Education and Welfare, Public Health Service Tab 51 NDA 17-463, September 19, 194, To: Schumann, PhD, From: J. Richard Crout, MD	
7647		Motrin 17-463, Three-Month-Update,- LFROOI01478,-Vol. I NDA 17-463, Motrin Tablets, (ibu) BI - annual report, September 10, 1976, LFROOI07593, Vol. 1.1	
7648		NDA 17-43, Motrin, Three Month Update, LFROOI01939, Vol. II NDA 17-463, Side Effects and Dose Level for Motrin Protocol 012 173, 8/8/74	
7649		NDA 17-463, Motrin Update, LFROOI02924, Vol. IV	
7650		Motrin Osteoarthritis Study - Table 41 Protocol 320, LFR00103190	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
7651		CI4-171, Upjohn, Initial Clinical Report - Rheumatoid Arthritis	Lacks authentication (Rule 901)
7652		C27-136, Adverse Reactions and concomitant Therapy, LFR 00025190	Lacks authentication (Rule 901)
7653		CI5-64, Upjohn, Initial Clinical Report - Rheumatoid Arthritis LFROOOI9750	Lacks authentication (Rule 901)
7654	1976	Motrin (ibu, U-18,573), NDA 17-463, First Quarterly Update Drug Experience Reports, FD-1639	
7655		Motrin Tablets, NDA-17-463, (ibu) Bi-Annual Report, September 10, 1976, Vol. II	
7656	1/29/1985	NDA 19-012, Nuprin Tablets Adverse Reactions, ADR's from Clinical Trials in Elderly Patients, January 29, 1985, Vol. 27	
7657	1976	NDA 17-463, Motrin Tablets (ibu) Bi-Annual Report, March 12, 1976 Vol. IV	
7658		Department of Health, Education, and Welfare, Public Health Service, To: Dr. Schumann, From J. Richard Crout, M.D., LFR00149316	
7659	9/30/1981	Motrin, NDA 17-463, LFR00121007, Reaction, Erythema Multiforme Motrin Tablets, NDA 17-463, (ibu) Progress Report, Vol. 6 - Adverse Reactions, September 30, 1981, LFR00125727	
7660		Motrin Tablets, NDA 17-463, Reaction Stevens Johnson Syndrome LFR00126730	
7661	7/20/1992	Index of FDA 1639s Being Submitted for the Time Period 07/11/1991 through 07/20/1992, Motrin Tablets NDA 17-463	Lacks authentication (Rule 901)
7662		NO EXHIBIT	
7663		Package Insert Children's Motrin Rx, PDR1994 - 2005	
7664		21 CFR 201.57, Federal Regulations, The Federal Register	
7665		21 CFR 314.70, Federal Regulations, The Federal Register	
7666	1999	Waller, P. Pharmacoepidemiology and Drug Safety, "Responding to Drug Safety Issues", 8:, 535-552, (1999)	
7667	1999	Sheridan, R.L., et. al., J Burn Care Rehabil, "Management of Severe Toxic Epidermal Necrolysis in Children", 20:497 - 500, (1999)	

Exh No.	Date	Description	Defendants' Objections
7668	2000	PDR 2000, Physicians Desk Reference, Zithromax, Pfizer Inc. 12389	
7669	2004	Bextra, November 2004, LAB-0266-4.0	
7670	3/17/1999	Federal Register, Part II Department of Health and Human Services 21 CFR, Part 20 I, et al., March 17, 1999	
7671		Mockenhaupt, M., et al., The Journal of Rheumatology, "The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated With Nonsteroidal Antiinflammatory Drugs: A Multinational Perspective	
7672		Foreign Labeling, Dolormin for Children	Lacks authentication (Rule 901)
7673		Package Insert Adult Motrin Rx 1982 - 2000	
7674		Package Insert Adult Motrin OTC NSAIDS (Adult) 1978 - 1989	
7675	1985	Bigby, M., et al., J Am Acad Dermatol, "Cutaneous reactions to Nonsteroidal anti-inflammatory drugs", 12:866-876 (1985)	
7676	1984	Stem, R., et al., JAMA, "An Expanded Profile of Cutaneous Reactions To Nonsteroidal Anti-inflammatory Drugs", 252:1433-1437, (1984)	
7677		Ibuprofen (Adult) 1978 - 1989	
7678		Ibuprofen (Adult) 1990 - 1996	
7679		Ibuprofen (Adult) 1997 - 2002	
7680		NAIDS I Ibuprofen Pediatrics	
7681		From Dr. Salisbury Report and Supporting Documents in Lofton	
7682		Expert Report of Roger E. Salisbury, M.D. (Lofton v McNeil and J&J)	
7683		Curriculum Vitae for Roger E. Salisbury, M.D.	
7684		List of Materials Reviewed in Lofton Report (Pg 2, Para. 8)	
7685	2/15/2005	Citizen Petition to Request Risk Assessment of SJS & TEN, dated Feb. 15, 2005	
7686	4/7/2005	FDA Food & Drug Administration- -FDA News- - "FDA Announces Series of Changes to the Class of Marketed Non-Steroidal Anti-inflammatory Drugs (NSAIDs) dated April 7, 2005	

Exh No.	Date	Description	Defendants' Objections
7687		FDA Questions and Answers of Regulatory Actions for the COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflannnatory Drugs (NSAIDs)	
7688		Department of Health & Human Services NDA Labeling Revision Request	Lacks authentication (Rule 901)
7689	6/22/2006	FDA Response Letter to Dr. Roger Salisbury Docket No. 2005P-0072/CPI. Dated June 22, 2006	
7690	4/25/2005	Roujeau, M.D., Jean-Claude, Video Deposition, Madden vs Wyeth pages 2-5, 102-105, 106-109, 110-113. April 25, 2005	
7691	5/13/2005	Stern, M.D., Robert, Video Deposition, Madden vs Wyeth pages 2-5, 154-157,162-165. May 13, 2005	
7692	9/14/2005	Madden vs Wyeth Memorandum Order pages 651, 655, 656 Sept. 14, 2005	
7693	9/14/2005	Madden vs Wyeth Memorandum Order Dr. Stern Statement pages 651, 655, 656 Sept. 14, 2005	
7694		Mockenhaupt, et al., "Stevens Johnson Syndrome", page 2239. SCAR Study Group	
7695	2003	Mockenhaupt, et al., "The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Antiinflammatory Drugs: A Multinational Perspective", The Journal of Rheumatology Pages 2234-2240 (2003).	
7696	1995	Kelly, Judith Parsells, et al., "An International Collaborative Case-Control Study of Severe Cutaneous Adverse reactions (SCAR) Design and Methods", Vol. 48, No.9 pages 1099-1108 (1995)	
7697	1995	Roujeau, M.D., Jean-Claude, et al., "Medication use and the Risk of Stevens- Johnson syndrome or toxic Epidermal Necrolysis", The New England Journal of Medicine Vol. 333, No. 24 pages 1600-1607 (1995)	

Exh No.	Date	Description	Defendants' Objections
7698	2002	Dunant, MS, Ariane Auquier, et al., "Correlations Between Clinical Patterns and Causes of Erythema Multiforme Majus, Stevens-Johnson Syndrome, and Toxic Epidermal Necrolysis", American Medical Association pages 1019-1024 (2002)	
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7700	1989	toxic epidermal necrolysis" American Academy of Dermatology Vol. 21, No.2, Part 1 pages 317-322\ (1989)	
7701	2004	Title 21- Food and Drugs Chapter 1- Food and Drug Administration, Department of Health and Human Services, Sub Chapter C- Drugs: General, Part 20 I-Labeling. 21 CFR 201.56 Lexis pages 1-3 (2004)	
7702	2004	Title 21- Food and Drugs Chapter 1- Food and Drug Administration, Department of Health and Human Services, Sub Chapter C- Drugs: General- Part 201: Labeling. Subpart B. 21 CFR 201.57 Lexis (2004)	
7703	2004	Title 21- Food and Drugs Chapter 1- Food and Drug Administration, Department of Health and Human Services, Sub chapter D- Drugs for Human Use, Part 314.70, pages 1-5 (2004)	
7704	1999	Title 21- Over-the Counter Human Drugs; Labeling Requirements; Final Rule- Food and Drug Administration, Department of Health and Human Services. Federal Register Vol. 64, No. 51, pages 13254-13303. (1999)	
7705	2001	OTC Labeling: Questions and Answers, FDA, DHHS pages 1-4 (2001)	
7706		Excerpts of Adult Motrin Rx Labeling; NDA 17-463/S-104 pages 1-17	
7707	2000	Excerpts of Adult Motrin OTC Labels, RX PDR-1999, OTC PDR -2000, RX PDR- 2000,	
7708		Excerpts of Children's Motrin Rx Labeling; Letter to McNeil consumer	

Exh No.	Date	Description	Defendants' Objections
7709		Healthcare NDA 20-516/S-004, NDA 20-60IIS-002, NDA 20-602/S-003,NDA 20-603/S-002 Sept. 13, 1999. RX PDR 1999- RX and OTC labeling.OTC PDR- 2000- OTC Children's + Infant's Motrin; RX PDR- 2000- Children's and Infant's Motrin	
7710	1997	Engelhardt, M.D., S. L., et al., "Toxic Epidermal Necrolysis: An Analysis of Referral Patterns and Steroid Usage", Journal of Burn Care & Rehabilitation Vol. 18, No.6 pages 520-524 (1997)	
7711	1997	Murphy, M.D. Joseph T., et al., "Toxic Epidermal Necrolysis", Journal of Burn Care & Rehabilitation Vol. 18, No.5 pages 417-420 (1997)	
7712	2000	PDR 2000, Zithromax pages 2389-2391	
7713	Nov-04	Bextra Labeling; Valdecocix tablets pages 1-17 November 2004	Lacks authentication (Rule 901)
7714		Inlingua: Dolormin for Children; User information, Questions and Answers;	Lacks authentication (Rule 901)
7715		Instructions for Usage	Lacks authentication (Rule 901)
7716	5/20/2004	Langstaff vs. McNeil Deposition Pages 518-557 May 20, 2004	Lacks authentication (Rule 901)
7717		Docket no. 2005P-0072/CPI	Lacks authentication (Rule 901)
7718	1994	Serious Skin Reactions In BUFS Requiring Hospitalization With Discharge Diagnoses BUFS Final Study Report; Subject ID: #16911811, #64052933,#91584555, #300024, #38932166; Medical Officer Review NDA 20-516(Supplement to NDA 19-842) pages 1-29 (1994)	
7719		Regulatory Copy: Pedia-Profen Ibuprofen Suspension NDA 19-842; The Boston University Fever Study: And Assessment of the Safety of PediatricIbuprofen (Interim Report- April 1992); FDA Spontaneous Reporting System pages 25-36; Overview of Pediatric Ibuprofen Study 90-056; Protocol Assessment	
7720		of the Safety of Pediatric Ibuprofen (Dec. 20 1990)	

Exh No.	Date	Description	Defendants' Objections
7721		Serious Skin Reactions Not Requiring Hospitalization In BUFS; Summary of Adverse Clinical Experience pages 10-16; Application To Market A New Drug For Human Use Or An Antibiotic For Human Use; Children's Motrin Ibuprofen Suspension Tables 1-9: Specific Problems Prompting an Outpatient doctor Visit Among 4604 Participants Seen for "Other" Reasons in the Four Weeks Following	
7722		Enrollement According to Treatment Group	Lacks authentication (Rule 901)
7723	11/1/1993	Anthony Temple Letter. BUFS Final Report. November 1, 1993	
7724		SRS 1969 to 1997 Ibuprofen Liver Complications	Lacks authentication (Rule 901)
7725		1997 Through 2001 AERS Ibuprofen Liver Complications	Lacks authentication (Rule 901)
7726	2002	2002 AERS Ibuprofen Liver Complications	Lacks authentication (Rule 901)
7727	2003	2003 AERS Ibuprofen Liver Complications	Lacks authentication (Rule 901)
7728	2004	2004 AERS Ibuprofen Liver Complications	Lacks authentication (Rule 901)
7729	11/1/1993	BUFS Final Report to Anthony Temple, M.D.-McNeil. November 1, 1993	
7730		Table G-BUFS Final Report: Case By Case Listing of Discharge Diagnoses, ppl-21	
7731	2/27/2006	FDA Medical Officer Review: Risks of SCAR with Provigil by. Joseph M. Porres,M. D. Consult #819, received December 21, 2005 from HFD-130. pp 1-28.February 27, 2006	Lacks authentication (Rule 901)
7732	2006	Excerpts of Transcript from Center for Drug Evaluation and Research. Psychopharmacologic Drugs Advisory Committee. 8:00 A.M.Monday March 23, 2006	Lacks authentication (Rule 901)
7733	2007	FDA Drug, Safety Newsletter Volume I Issue I pp. 1-10 Fall 2007	
7734		Plaintiff's Expert Table of Total Cases hospitalized with cutaneous and mucocutaneous Hospital Cases with Selected Discharge Diagnosis Judged as Possibly Related to Ibuprofen from BUPs	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
7735		Boston Fever Study Tables A thru F. BUPS Enrollment/Consent Form, Medication Bottle Label, Summary of Adverse Clinical' Experience pp 9-17. Feb. 1, 1991-Nov. 1, 1991	
7736		Serious Skin Reactions in BUPS Requiring Hospitalization with Discharge Diagnoses. BUPS Final Study Report. Subject # 91584555, # 64052933, # 300021.0, # 16911811, # 38932166, # 0000072-05, # 53944826, # 84295014, # 70760725	
7738		Serious Skin Reactions Not Requiring Hospitalization in BUFS. Subject ID # 0028221779, #0028221780. New Drug Application McNeill Consumer Products Company. Ibuprofen- Children's Motrin Suspension Liquid. IND 27,731 NDA 20-135. December 22, 1993. Tables I thru 9 of Specific Problems Promoting an Outpatient Doctor Visit Among 4606 Participants Seen for Other Reasons in the Four Weeks Following Enrollment According to Treatment Group	
7739		NO EXHIBIT	
7740		Children's.Motrin Ibuprofen Suspension NDA 20-516 Safety Update. November 11, 1994	
7741	3/28/1995	Arthritis and Nonprescription Drugs Advisory Committees on the Switch of Children's Motrin Ibuprofen Suspension from Prescription to Nonprescription Status. Temple Presentation Slides and Transcript of Non-Prescription Drug Advisory Committee. March 28, 1995	
7742		Transcript of NDAC Meeting: Rx to OTS Switch of Children's Motrin March 28, 1995	
7743		FD-356H New Drug Application for Coated Compressed Tablets Motrin (Ibuprofen, U-IS,573) Volume 1.1 Part 1- Table of Contents. Part 2- Expanded Summary and Evaluation	
7744		Motrin Package Insert. Motrin 400 mg Tablets (Ibuprofen, Upjohn) Effective in the Long-Term Symptomatic Treatment of Osteoarthritis and Rheumatoid Arthritis. Pp 1-47. Motrin (Ibuprofen) Package Inserts	
7748	9/19/1974	FDA Approval Letter to PNU-Motrin Rx. NDA 17-463. Sept. 19, 1974	

Exh No.	Date	Description	Defendants' Objections
7749	12/16/1974	NDA 17-463 Motrin Three Month Update (Medical Copy) Volume I Progress Report. Protocol 007. Dec. 16, 1974	
7750	9/10/1976	NDA 17-463 Motrin Tablets (Ibuprofen) Bi-Annual Report (Medical Copy) Vol. I.Sept. 10, 1976	
7751	8/8/1974	NDA 17-463 Motrin Three Month Update (Medical Copy) Vol.II. Protocols 007A, 007B, 008, 008A, 008B, Aug. 8, 1974	
7752	8/8/1974	NDA 17-463 Side Effects for Dose Lever For Motrin Protocol 012 Aug 8,1974 Motrin Osteoarthritis Study	Lacks authentication (Rule 901)
7753		NDA 17-463 Motrin Three Month Update (Medical Copy) Vol. IV Protocol 014, 016,020	Lacks authentication (Rule 901)
7754		Motrin Osteoarthritis Study pp. 255	Lacks authentication (Rule 901)
7755		Initial Clinical Report- Rheumatoid Arthritis, C14-171 thru C14-184	Lacks authentication (Rule 901)
7756		Case Report Form from Motrin Rx Study of SCAR - Protocol #7	Lacks authentication (Rule 901)
7757		Initial Clinical Report - Rheumatoid Arthritis, C15-64 thru C15-76	Lacks authentication (Rule 901)
7758		Drug Experience Reports from Motrin Clinical Trials of SCAR	Lacks authentication (Rule 901)
7759	9/10/1976	Motrin Tablets Ibuprofen NDA 17-463, Bi Annual Report 9-10-76, Vol. II	
7760	1/29/1988	Nuprin - Adverse Reactions from Clinical Trials on Elderly Patients January 29, 1988	Lacks authentication (Rule 901)
7761	3/12/1976	NDA 17-463, Motrin Tablets, Bi-Annual Report, March 12,1976, Vol. IV	Lacks authentication (Rule 901)
7762		FDA Regulations - Applications for FDA Approval to Market a New Drug, Subpart B - Applications 314.80,11-26-2003	
7763		FDA Letter to PNU - Motrin Trial- FDA Investigation, Food and Drug Administration Mr. Clarence V. Bozarth inspection July, 1973	Lacks authentication (Rule 901)
7764		NO EXHIBIT	
7765	1/29/1980	Motrin NDA 17-463, Clinical Trial- Case Report form of Erythema multiforme, Case 1282, 1-29-80	Lacks authentication (Rule 901)
7766		Motrin Tablets, Ibuprofen Progress Report Vol. 6 - Post-Market Adverse Reactions NDA 17-463, 09-30-1981	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
7767		Motrin Tablets, Ibuprofen NDA 17-463, Post-Marketing Report of Stevens-Johnson Syndrome, Case 1645, 04-27-1981	Lacks authentication (Rule 901)
7768		PNU - Post Marketing Submission of SJS case to FDA, Index of FDA 1639s Being Submitted for the Time Period 07-01-1991 thru 07-20-1992, Motrin Tablets, NDA 17463, 15 Day Alert NDA 17-463,	Lacks authentication (Rule 901)
7769	7/1/1994	Voluntary & Literature Medical Events, Motrin Tablets, NDA 17-463, Time Period 07-01-1993 thru 06-30-1994, 15 Day Alert Follow-up Voluntary & Literature Medical Events 07-01-1994 thru 07-16-1995	Lacks authentication (Rule 901)
7770	1996	Index of Submission to FDA During the Time Period 07-19-1995 thru 07-19-1996	Lacks authentication (Rule 901)
7771	11/14/1997	0889498A IS Day Alert ADE Report Ibuprofen Court Filing Statements Document 960317819, Medical Records, McNeil Submission of Lawsuit filed again PNU for Ibuprofen-induced SJS case to FDA with blindness on 11-14-1997	Lacks authentication (Rule 901)
7772	2003	O'Connor N., et al., 01 Med, "Hepatocellular Damage from Non-Steroidal AntiInflammatoryDrugs," Vol. 96, No. II, pp. 787-91 (2003)	
7773		NO EXHIBIT	
7774	2003	Teoh N., et al., Clin Liver Dis, "Hepatotoxicity Associated with Non-Steroidal Anti-Inflammatory Drugs," Vol. 7, pp. 401-13, (2003)	
7775	2002	Chitturi S., et al., Seminars in Liver Dis, "Hepatotoxicity of Commonly Used Drugs: Non-steroidal Anti-Inflammatory Drugs, Antihypertensives, Antidiabetic Agents, Anticonvulsants, Lipid-Lowering Agents, Psychotropic Drugs," Vol. 22, No.2, pp. 169-83, (2002)	
7776	2002	Sgro C., et al., Hepatology. "Incidence of Drug-Induced Hepatic Injuries: A French Population-Based Study," Vol. 36, No.2, pp.451-5, (2002)	

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7777	2002	Kirchheiner J., et al., Clin Pharm Therapeutics, "Enantiospecific Effects of Cytochrome P450 2C9 Amino Acid Variants on Ibuprofen Pharmacokinetics and on the Inhibition of Cyclooxygenases I and 2," Vol. 72, No.1, pp. 62-75, (July 2002) .	
7778	2002	Strassburg C., et al., Liver Disease, "Developmental Aspects of Human Hepatic Drug Glucuronidation in Young Children and Adults," Vol. 50, pp. 259-65, (2002)	
7779	2001	Chitturi S., et al., Seminars in Gastrointestinal Dis, "Drug-Induced Cholestasis," Vol. 12 No.2 pp. 113-24, (2001)	
7780	2001	Evans A., Clin Rheumatol, "Comparative Pharmacology of S(+)-Ibuprofen," Supp 1, pp. S9-14, (2001)	
7781	2001	Hernandez-Diaz S., et al., Amer J. of Med, "Epidemiologic Assessment of the Safety of Conventional Nonsteroidal Anti-Inflammatory Drugs," Vol. 110, No. 3A, pp. 20S-7S, -2001	
7782	2000	Laurent S., et al., Liver, "Subfulminant Hepatitis Requiring Liver Transplantation Following Ibuprofen Overdose," Vol. 20 pp. 93-4 (2000)	
7783	2000	Mascagni P., et al., Eur Cytokine Netw, "R-and S-Isomers of Non-steroidal AntiInflammatory Drugs Differentially Regulate Cytokine Production," Vol. 11, No.2, pp. I 85-92, (2000)	
7784	1999	Luster M., et al., Critical Reviews in Toxicology, "Tumor Necrosis u Factor and Toxicology," Vol. 29, No.5, pp. 491-511, (1999)	
7785	1999	Pessayre D., et al., Cell Biology and Toxicology, "Hepatotoxicity Due to Mitochondrial Dysfunction," Vol. IS, pp. 367-73, (1999)	
7786	1998	Riely III T., et al., Am J of Gastroenterology. "Ibuprofen-Induced Hepatotoxicity in Patients with Chronic Hepatitis C: A Case Series," Vol. 93, No.9, pp. 1563-5 (1998)	
7787	1998	Wanner G., et al., Am J of Surg, "Differential Effect of Cyclooxygenase Metabolites on Pro-Inflammatory Cytokine Release by Kupffer Cells after Liver Ischemia and Reperfusion," Vol. 175, pp. 146-51, (1998)	

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7788	1998	Masubuchi Y., et al., J of Pharmacology and Experimental Therapeutics, "Structural Requirements for the Hepatotoxicity of Non-Steroidal Anti-Inflammatory Drugs in Isolated Rat Hepatocytes," Vol. 287, No. I, pp. 208-13, (1998)	
7789	1996	Hamman M., et al., Pharmaceutical Research; "Regioselective and Stereoselective Metabolism of Ibuprofen by Human Cytochrome," Vol. 36, pp. 500-4, (1996)	
7790	1996	Evans A., J Clin Pharmacol, "Pharmacodynamics and Pharmacokinetics of the Profens: Enantioselectivity, Clinical Implications, and Special Reference to S(+)-Ibuprofen," Vol. 36, pp. 7S-15S, (1996)	
7791	1996	Alam I., et al., Am J of Gastroenterology, "Vanishing Bile Duct Syndrome Temporally Assoc with Ibuprofen Use," Vol. 91, No. 8, pp. 1626-30, (1996)	
7792	1996	Manoukian A., et al., Drug Safety. "Nonsteroidal Anti-Inflammatory Drug-Induced," Vol. I, pp. 64-71, (1996)	
7793	1995	Pessayre D., J of Hepatology, "Role of Reactive Metabolites in Drug-Induced Hepatitis," Vol. 23, Supp. 1, pp. 16-24, (1995)	
7794	1995	Boelsteli U., et al., Critical Rev in Toxicology, "Idiosyncratic Liver Toxicity of Non-Steroidal Anti-Inflammatory Drugs: Molecular Mechanisms and Pathology," Vol. 25, No. 3, pp. 207-35, (1995)	
7795	1995	Fry S., et al., Drug-Induced Liver Disease, "Hepatotoxicity of Analgesics and Anti-Inflammatory Agents," Vol. 24, No. 4, pp. 875-905, (1995)	
7796	1994	Rodriguez L., et al., Arch Intern Med, "Acute Liver Injury Associated with Non-Steroidal Anti-Inflammatory Drugs and the Role of Risk Factors," Vol. 154, pp. 311-6, (1994)	
7797	1994	Rekka E., et al., Arch Toxicol, "Induction of Hepatic Microsomal CYP4A Activity and of Peroxisomal β -Oxidation by Two Non-Steroidal Anti-Inflammatory Drugs," Vol. 68, pp. 73-8, (1994)	

Exh No.	Date	Description	Defendants' Objections
7798	1994	Jurima-Romet M., et al., Toxic in Vitro, "Comparative Cytotoxicity of Non-Steroidal Anti-Inflammatory Drugs in Primary Cultures of Rat Hepatocytes," Vol. 8, No. I, pp.55-66, (1994)	
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7800	1993	Bendele A., et al, Toxicology Pathology, "Hepatocellular Proliferation in Ibuprofen Treated Mice," Vol. 21, No. I, pp. 15-20, (1993)	
7801		Chen C., et al., The Jour of Pharmacology & Experimental Therapeutics, "Stereoselective Disposition of Ibuprofen in Patients with Renal Dysfunction," Vol. 268, No.2, pp. 509-4,	
7802	1992	Rabinovitz M., et al., Am J of Gastroenterology, "Hepatotoxicity of Non-Steroidal AntiInflammatory Drugs," Vol. 87, No. 12, pp. 1696-1704, (1992)	
7803	1992	Friis H., et al., J of Internal Med, "Drug-Induced Hepatic Injury: an Analysis of 1100 Cases Reported to The Danish Committee on Adverse Drug Reactions Between 1978 and 1987," Vol. 232, pp. 133-8, (1992)	
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7806	1991	Chen C., et al., J FormosanMed Assoc, "Metabolic Inversion of Stereoisomeric Ibuprofen in Man," Vol. 90 No.5, pp. 437-42, (1991)	
7807	1990	Zimmerman H., Siminars in Liver Disease, "Update of Hepatotoxicity Due to Classes of Drugs in Common Clinical Use: Non-Steroidal Drugs, Anti-Inflammatory Drugs, Antibiotics, Anti-Hypertensives, and Cardiac and Psychotropic Agents," Vol. 10, No.4, pp. 322-38, (1990)	

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7808	1990	Muller S., et al., Chirality, "Metabolic Chiral Inversion of Ibuprofen in Isolated Rat Hepatocytes," Vol. 2, pp.74-8, (1990)	
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7811	1985	Sorensen E., et al., J of Toxicology and Environmental Health, "Relative Toxicities of Several Nonsteroidal Anti-inflammatory Compounds in Primary Cultures of Rat Hepatocytes," Vol. 16, pp. 425-40, (1985)	
7812	1980	Itoh S., et al., Hepato-Gastroenterol, "Drug-Induced Liver Injury and Microsomal Arylamidase Activity in Needle Biopsy of Human Liver," Vol. 27, pp. 423-31, (1980)	
7813	1978	Sternlieb., et al., N.Y. State J of Med., "Stevens-Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen," pp. 1239-42, (1978)	
7814	1977	Bravo J., et al., Ann of Internal Med, "Fatty Liver and Pleural Effusion with Ibuprofen Therapy," Vol. 87, No.2, pp. 200-1, (1977)	
7815	1977	Stempel D., et al., J of Pediatrics, "Lymphopenia and Hepatic Toxicity with Ibuprofen," Vol. 90, No.4, pp.657-8, (1977)	
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Exh No.	Date	Description	Defendants' Objections
7818		NO EXHIBIT	
7819	2005	Hopkins, R and Stephen Brett, Current Opinion in Critical Care, "Chronic Neurocognitive Effects of Critical Illness," Vol. 11, pp. 369-375, (2005)	
7820		Semmler, Alexander, et al., Journal of Chemical Neuroanatomy, "Systematic Inflammation Induces Apoptosis with Variable Vulnerability of Different Brain	
7821	2005	Milbrandt. E.B. and Derek C. Angus, Current Opinion in Critical Care, "Potential Mechanisms and Markers of Critical Illness-Associated Cognitive Dysfunction," Vol. 11, pp.355-359, (2005)	
7822	2005	Rosenberg, M., et al., Burns, "Neuropsychological Outcomes of Pediatric Burn Patients Who Sustained Hypoxic Episodes," Vol. 31, pp. 883-889 (2005)	
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7824	2004	Hopkins, R., et al., Journal of the International Neuropsychological Society, "Quality of Life, Emotional, and Cognitive Function Following Acute Respiratory Distress Syndrome," Vol. 10, pp. 1005-1017, (2004)	
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7828	2003	Jackson, James C., et al., Crit Care Med, "Six-Month Neuropsychological Outcome of Medical Intensive Care Unit Patients," Vol. 31, No.4, pp. 1226-1234, (2003)	
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7932		Marquis, K.A., et al., American Journal of Respiratory and Critical Care Medicine, Neuropsychological Sequelae in Survivors of ARDS Compared with Critically Ill Control Patients (abstract), Vol. 161, pp. A383, (2000)	
7933		NO EXHIBIT	
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8047	1996	1996-PDR-OTC Children’s Motrin	
8048	1997	1997- PDR-OTC-Children’s Motrin	
8049	2006	2006- PDR-Children’s Motrin	
8050		Inlingua- Insert for Dolormin for Children, Ibuprofen Juice	Lacks authentication (Rule 901)
8051		Children’s Motrin Suspension Final Printed Labeling (727/95)(LFR00334676-LFR00334689)	
8052		McNeil Consumer Products Company Clinical Study Report Protocol 90-056 (Phase IV)(MC074066-MC074185)	
8053		Patient Data Listing for Study 90-056- Children’s Motrin Ibuprofen Suspension (MOT00000761-00000762)	
8054		FDA letter to Vivian Chester regarding Sine Aid	
8055	8/17/1993	8/17/83- Memo to Arthritis Advisory Committee from FDA regarding Adverse Reaction Reports (MC067313-MC067315)	
8056	5/31/1984	5/31/84- Letter to Robert Temple re Ibuprofen-Summary Basis of Approval (MC067066-MC067090)	
8057	6/6/1984	6/6/84- Letter from Thomas Gates to Healthwriter regarding change from prescription to over-the-counter status of ibuprofen (MC067171)	
8058	6/19/1984	6/19/84- Ibuprofen Petition for Reconsideration of Approval of New Drug Applications (MC067238-MC067247)	
8059	8/22/1984	8/22/84- Letter to Tony Temple from Goldfrank, Weisman & Howland (MC065014-MC065015)	

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8062	3/31/1988	3/31/88- Letter from Thomas Gates to FDA enclosing NDA for Ibuprofen Pediatric Suspension (MC06A000796)	
8063	3/31/1988	3/31/88- Ibuprofen Pediatric Suspension New Drug Application	
8064	3/14/1989	3/14/89- Memo to Tony Temple Regarding Labeling and Insert for Ibuprofen Pediatric Suspension (MC071665)	
8065	12/22/1989	12/22/89- File copy regarding Pediafen Suspension	Lacks authentication (Rule 901)
8066	12/20/1990	12/20/90- Protocol- The Boston University Fever Study (MC070223-MC070233; MC01A000477-MC01A000493)	
8067	Apr-92	4/92- The Boston University Fever Study: An Assessment of the Safety of Pediatric Ibuprofen (Interim Report) (MC12A001046-MC12A001048)	
8068	6/11/1992	6/11/92 McNeil Letter Re OTC Switch of Pedia-Profen (MC070811-MC070852)	
8069	2/12/1993	2/12/93- BUFS Questionnaire (MOT00000765-MOT00000766)	
8070		BUFS Data Listing for Protocol (MC044005-MC04408)	
8071	10/29/1993	10/29/93-Children's Motrin OTC Dosing (MC071501)	
8072	Nov-93	11/93- The Boston University Fever Study Draft of Final Report (MC070645-MC070737; MC070840-MC070852)	
8073		BUFS Questionnaire (Alexander Bordeaux)	Lacks authentication (Rule 901)
8074	11/14/1994	11/14/94- Facsimile to Vivian Chester from Susan Guckenheimer regarding Motrin Label (MC013A000754-MC013A000775)	
8075	5/9/1995	5/9/95- FDA letter to Willie Pagsuyin regarding promotional materials for Motrin pediatric products	
8076	5/31/1995	5/31/95 - Revised Proposed OTC Labeling For Children's Motrin Suspension (MC071324 - MC071327)	

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8077	6/16/1995	6/16/95- Fax from DDMAC to Willie Pagsuyin regarding labeling (MC063712-MC06316)	
8078	11/20/1995	11/20/95- Revised Q&As regarding Children's Motrin Suspension (MC070933-MC070946)	
8079	4/16/1996	4/16/96- Letter from McNeil to FDA with electronic copy of final printed labeling (combined package insert) for pediatric Motrin products & draft labeling per FDA Approval Letter (MC12A001438-MC12A001465)	
8080	2/25/1997	2/25/97- Protocol of Assay (LFR00246220-LFR00246268)	
8081	10/3/1997	10/3/97- Regulatory Copy of Motrin IB Tablets & Motrin IB Caplets Annual Report (LFR 00246082-LFR00246219)	
8082	5/7/1998	5/7/98- Children's Motrin Suspension- Method Validation Materials (LFR00334784-LFR00334860)	
8083	12/20/2001	12/20/01- Regulatory Copy- Children's Motrin Suspension- Final Printed label (MC0A000622-MC02A000633)	
8084	6/9/2003	6/9/03- Release of Draft Guidance Document & Guidance for Industry- Basic Product Monograph Information for NSAIDs (MOT00007205-MOT00007229)	
8085	3/24/2004	3/24/04- email from Mary Joan Denisco- re Review Motrin Rx Suspension label for FDA Response	
8086	2/15/05-	2/15/05-Citizen's Petition	
8087	4/6/2005	4/6/05- FDA Decision Memorandum regarding Agency action regarding NSAIDs and cardiovascular risk	
8088	6/15/2005	6/15/05- FDA letter regarding "allergy alert" and SJS warnings (MOT00007466-MOT00007474)	
8089	8/5/2005	8/5/05-FDA Response to Citizen's Petition	
8090	5/27/2010	5/27/10- Transcript of Hearing of the House Oversight & Government Reform Committee regarding "Johnson and Johnson's Regall of Children's Tylenol and Other Children's Medicines."	
8091	5/27/2010	5/27/10- Testimony of Colleen Goggins Before the U.S. House of Representatives	

Exh No.	Date	Description	Defendants' Objections
8092	5/27/2010	5/27/10- Statement of Joshua M. Sharfstein Before the U.S. House of Representatives	
8093		NDA 19-012 Nuprin, Haltran, Motrin IB Annual Report (LFR00246269-LFR00246338)	
8094	1/29/1995	1/29/95-Medwatch Report (MC074063)	
8095	3/31/1995	3/31/95-Medwatch Report (MC12A000937)	
8096	5/15/1995	5/15/95- Medwatch Report (MC11A000972)	
8097	5/28/1996	5/28/96- Medwatch Report (MC04A001974)	
8098	7/22/1996	7/22/96-Medwatch Report re Kiley Wolfe (MOT0001153)	
8099	8/21/1996	8/21/96- Medwatch Report re Kiley Wolfe (MOT0001153)	
8100	11/10/1997	11/10/97 Medwatch Report (MC073972)	
8101	9/22/1998	9/22/98 Medwatch Report (MOT00015853)	
8102	1/20/2000	1/20/00- Medwatch Report- (MC079396)	
8103	2/22/2000	2/22/00- Medwatch Report- (MC079438)	
8104	4/18/2003	4/18/03- Medwatch Report- (MC079465)	
8105	6/20/2003	6/20/03- Medwatch Report- (MC079465)	
8106		Adverse Drug Experience Reporting Procedures (MC000035-MC000043)	
8107		Children's Motrin Q&A (MCO71195-MC71199)	
8108		Printouts from www.motrin.com	Lacks authentication (Rule 901)
8109		Summary of Product Characteristics- Inpren 5% Gel (INT00000338-INT00000365)	Lacks authentication (Rule 901)
8110		21 CFR Section 312.32- IND Safety Report	
8111		Motrin Advertisement - "In Childhood Fever, Because Safety Is Your First Concern"	Lacks authentication (Rule 901)
8112		CV of Willie Pagsuyin	
8113		CV of Peter Bell	
8114		CV of Eileen Helzner	
8115		International Safety Data - MC0SA000218 - 000219	
8116	8/24/2006	8/24/06- Letter from William Balistreri, M.D.	Lacks authentication (Rule 901)
8117	9/30/2010	Testimony of Mr. William C. Weldon, Chairman and Chief Executive Officer at Johnson & Johnson before the Commission on Oversight and Government Reform in at the United States House of Representatives on September 30, 2010	

Exh No.	Date	Description	Defendants' Objections
8118		Article: Johnson & Johnson Sued by Oregon Claiming Secret Motrin Recall Risked Harm	
8119		Article: Regarding 2010 Recall of McNeil Medications	
8120		Children's Motrin Print Advertisements	Lacks authentication (Rule 901)
8121		Kiley Wolfe's School Records	
8122		Application for SSI Disability	
8123		Social Security Decision	
8124	3/4/2009	Wyeth v. Levine (Supreme Court Decision March 4, 2009)	
8125		Kiley Wolfe' Report Cards	
8126		Letters to and from Kiley and her dad, William Wolfe	
8127		Application for High School Independent Study Courses.	
8128	6/1/1996	Assurant Health Medical Lien in the amount of \$7,022.27 for services on June 1, 1996	
8129		State of Louisiana Medicaid Lien Letter of September 22, 2010 in the amount of \$1,493.08	
8130	2/15/2010	State of Louisiana Medicaid Lien Letter of February 15, 2010 in the amount of \$1,661.32	
8131		Fortis/Assurant Claims Information	
8132		Blue Cross Claim Summaries	
8133		Unicare Claim Summaries	
8134	1996	Medical Expenses / Out-of-Pocket Expenses: 1996	
8135	1997	Medical Expenses/ Out-of-Pocket Expenses: 1997	
8136	1998	Medical Expenses/ Out-of-Pocket Expenses: 1998	
8137	1999	Medical Expenses/ Out-of-Pocket Expenses: 1999	
8138	2000	Medical Expenses / Out-of-Pocket Expenses: 2000	
8139	2001	Medical Expenses/ Out-of-Pocket Expenses: 2001	
8140	2002	Medical Expenses/ Out-of-Pocket Expenses: 2002	
8141	2003	Medical Expenses/ Out-of-Pocket Expenses: 2003	
8142	2004	Medical Expenses/ Out-of-Pocket Expenses: 2004	

Exh No.	Date	Description	Defendants' Objections
8143	2005	Medical Expenses/ Out-of-Pocket Expenses: 2005	
8144	2006	Medical Expenses/ Out-of-Pocket Expenses: 2006	
8145	1995	1995 Explanation of Benefits from Time Insurance	
8146	1996	1996 Explanation of Benefits from John Hancock	
8147	1997	1997 Explanation of Benefits from Time Insurance	
8148	1998	1998 Explanation of Benefits from Fortis Insurance Company	
8149	1999	1999 Explanation of Benefits from John Hancock Ins. Co.	
8150	1999	1999 Explanation of Benefits from Fortis Insurance Company	
8151	1999	1999 Explanation of Benefits from John Hancock	
8152	2000	2000 Explanation of Benefits from John Hancock	
8153	2000	2000 Explanation of Benefits from Fortis Insurance Company	
8154	2000	2000 Explanation of Benefits from John Hancock	
8155	2001	2001 Explanation of Benefits from Unicare Life & Health Assoc. Services	
8156	2001	2001 Explanation of Benefits from Fortis Insurance Company	
8157	2002	2002 Explanation of Benefits from Fortis Insurance Company	
8158	2002	2002 Explanation of Benefits from Unicare	
8159	2004	2003 Explanation of Benefits from Fortis Insurance Company	
8160	2004	2004 Explanation of Benefits from Fortis Insurance Company	
8161	2004	2004 Explanation of Benefits from Unicare	
8162	2004	2004 Explanation of Benefits from Blue Cross	
8163	2005	2005 Explanation of Benefits from Fortis Insurance Company	
8164	2005	2005 Explanation of Benefits from Blue Cross	
8165	2005	2005 Explanation of Benefits from Assurant Ins. Company / Time Ins. Co..	

Exh No.	Date	Description	Defendants' Objections
8166	2006	2006 Explanation of Benefits from Assurant Ins. Company / Time Ins. Co..	
8167	2006	2006 Explanation of Benefits from Blue Cross	
8168	2007	2007 Explanation of Benefits from Assurant Ins. Company / Time Ins. Co..	
8169	2008	2008 Explanation of Benefits from Blue Cross	
8170		Cincinnati Children's Billing Records	
8171		Nemours Billing Records	
8172		Owen Scott Billing Records	
8173		Neuromedical Center Billing Records	
8174		CVS Pharmacy Billing Records	
8175		Baton Rouge Urology Clinic Billing Records	
8176		Louisiana Cardiology Associates Billing Records	
8177		Janet Leland's Diary and Phone Book	
8178	2004	Kiley's Medical Records of 2004	
8179		Junior Strength Motrin Label	
8180		Articles Re: Children's Motrin Over the Counter	
8181		Kiley's School Chronology	
8182		Article Re: Johnson and Johnson Reaches For a Band-Aid	
8183		Photographs of Kiley Wolfe before illness	
8184		Photographs of Kiley Wolfe while in Boston Children's Hospital	
8185		Photographs of Kiley Wolfe taken before and after transplant	
8186		Prescription For Antipyrine/Benzocaine (A/B OTC 15 ml)	
8187		Baptist Health Medical Records	
8188		Itemization/Documentation of Out-of-Pocket Expenses Incurred by William Wolfe	
8189		Children's Motrin Annual Report No. 1 regarding distribution (MC02A00816)	
8190		Children's Motrin Annual Report No. 2 regarding distribution (MC02A000895)	
8191		Children's Motrin Annual Report No. 3 regarding distribution (MC02A000895)	
8192		Children's Motrin Annual Report No. 8 regarding distribution (MC03A01332)	
8193		Children's Motrin Annual Report No. 4 (LFR0339726)	
8194		Children's Motrin Annual Report No. 5 Distribution Data (LFR01252361)	

Exh No.	Date	Description	Defendants' Objections
8195		Children's Motrin Annual Report No. 6 Distribution Data (LFR01252734)	
8196		Children's Motrin Annual Report No. 7 Distribution Data (LFR01253174)	
8197		Children's Motrin Annual Report No. 9 Distribution Data (LFR01258313)	
8198		Children's Motrin Annual Report No. 10 Distribution Data (LFR01258877)	
8199		Children's Motrin Annual Report No. 11 Distribution Data (LFR01261163)	
8200		Code Orange Campaign for Motrin (MOT01245364-MOT1245366)	
8201		Motrin IB 2003 Media Plan Budget Summary (MOT01245357)	
8202		Motrin IB 2004 Media Plan (MOT01245372)	
8203		Motrin IB 2005 Media Plan (MOT01245376)	
8204		Motrin IB 2006 Media Plan (MOT01245379)	
8205		Motrin IB 2007 Media Plan (MOT 01245383)	
8206		Motrin IB 2008 Media Plan (MOT01245384)	
8207	1996	1996 Advertisement "Introducing Children's Motrin" (MOT01245385)	
8208	1996	1996 Advertisement/Coupon "The 8-Hour Breakthrough in Breaking High Fever" (MOT01245386)	
8209	1998	1998 Advertisements regarding Children's Motrin (MOT01246388)	
8210		"Relief Pitcher" Advertisement (MOT01245388)	
8211		"Protects Her Turf" Advertisement (MOT01245389)	
8212		"Tell High Fever to Kiss Off" Advertisement (MOT01245390)	
8213		"She Got the Fever You Got the Cure" (MOT01245391)	
8214	2006	2006 "Flex Your Family Muscle" Advertisement	
8215		Motrin Peds Dye Free 2003 Media Plan Budget Summary (MOT01245393)	
8216		Children's Motrin 2004 Media Plan Budget Summary (MOT01245399)	
8217		Children's Tylenol 2005 Media Plan (MOT01245405)	
8218		Johnson & Johnson 2006 Pediatrics Franchise Media Plan (MOT0124540)	

Exh No.	Date	Description	Defendants' Objections
8219		Story Board "Child's World Full of Firsts"	
8220	1995	Gebhart, M., et al., Z Rheumatol, "Cutaneous side-effects of nonsteroidal anti-inflammatory drugs (NSAID)," Vol. 54, No. 6, pp. 405-412 (1995)	
8221		Galindo, C. et al., Rev. Esp. Enferm. Dig. "Acute pancreatitis associated with hepatotoxicity incuded by amoxicillin-clavulanic acid." Vol. 87, No. 8 pp. 597-600 (1995)	
8222	1995	Prieto, Paula, et al., Rev. Clin. Esp. "Bendazac hepatotoxicity: analysis of 16 cases," Vol. 195 No. 6, (1995)	
8223		Heathcote, J., Gastroenterologist, "Hepatotoxicity: newer aspects of pathogenesis and treatment," Vol. 3, No. 2, pp. 119-129	
8224	1995	Zaragoza, Marcet et al., Rev. Esp. Enferm Dig., "NSAID-induced hepatotoxicity: aceclofenac and diclofenac," Vol. 87, No. 6, pp. 472-475 (1995)	
8225	1995	Cheriyen, S., et al., Allergy Proc, "The outcome of Stevens-Johnson syndrome treated with corticosteroids," Vol. 16, No. 4, pp. 151-155 (1995)	
8226	1993	Pott, G, Z Gastroenterol, "Drug-induced cholestasis," Vol 31, Supp. 2, pp. 73-75 (1993)	
8227		Lee, WM, Aliment Pharmacol Ther, "Review article: drug-induced hepatotoxicity," Vol. 7, No. 5, pp. 477-485.	
8228	1993	Yoshimura T., et al., Biol Pharm Bull, "Diagnosis of drug allergy by the lymphocyte stimulation test with MTT (3-(4,5-dimethyl thiazol-2-yl), -2, 5-diphenyl tetrazolium bromide] assay," Vol. 15, No. 7, pp. 686-689 (1993).	
8229	1993	Vigouroux C, Rev Med Interne, "Disclosure of systemic lupus erythematosus in a case of hepatitis caused by ibuprofen," Vol. 14, No. 9, pp. 856-859 (1993).	
8230		Labels and/or package inserts and/or box label and/or physician desk reference entries relating to and for the years 1992 - 2008 for OTC Children's Motrin;	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
8231		Labels and/or package inserts and/or box label and/or physician desk reference entries relating to and for the years 1992 - 2008 for Prescription Children's Motrin;	Lacks authentication (Rule 901)
8232		Labels and/or package inserts and/or box label and/or physician desk reference entries relating to and for the years 1992 - 2008 for Pedia-Profen;	Lacks authentication (Rule 901)
8233		Labels and/or package inserts and/or box label and/or physician desk reference entries relating to and for the years 1992 - 2008 for Motrin (Adult);	Lacks authentication (Rule 901)
8234		Labels and/or package inserts and/or box label and/or physician desk reference entries relating to and for the years 1992 - 2008 for any other name of ibuprofen marketed by McNeil and/or Johnson & Johnson.	Lacks authentication (Rule 901)
8235		Labels and/or package inserts and/or box labels and/or PDR reference entries relating to Motrin marked by Upjohn or any other company from 1978 - 1994	Lacks authentication (Rule 901)
8236		Labels and/or package/inserts and/or box labels and/or PDR reference entries relating to Motrin marketed in foreign countries from 1994 - 2008.	Lacks authentication (Rule 901)
8237	1995	1995 Children's Motrin OTC Label/Box Label	
8238	1996	1996 Children's Motrin OTC Label/Box Label	
8239	1997	1997 Children's Motrin OTC Label/Box Label	
8240	1998	1998 Children's Motrin OTC Label/Box Label	
8241	1999	1999 Children's Motrin OTC Label/Box Label	
8242	2000	2000 Children's Motrin OTC Label/Box Label	
8243	2001	2001 Children's Motrin OTC Label/Box Label	
8244	2002	2002 Children's Motrin OTC Label/Box Label	
8245	2003	2003 Children's Motrin OTC Label/Box Label	
8246	2004	2004 Children's Motrin OTC Label/Box Label;	
8247	2005	2005 Children's Motrin OTC Label/Box Label;	
8248	2006	2006 Children's Motrin OTC Label/Box Label;	
8249	2007	2007 Children's Motrin OTC Label/Box Label;	
8250	2008	2008 Children's Motrin OTC Label/Box Label;	
8251	Various	1978, 1979, 1980 PDR and/or product insert re: Motrin;	
8252	1981	1981 PDR and/or product insert re: Motrin;	
8253	1982	1982 PDR and/or product insert re: Motrin;	
8254	1983	1983 PDR and/or product insert re: Motrin;	

Exh No.	Date	Description	Defendants' Objections
8255	1984	1984 PDR and/or product insert re: Motrin;	
8256	1985	1985 PDR and/or product insert re: Motrin;	
8257	1986	1986 PDR and/or product insert re: Motrin;	
8258	1987	1987 PDR and/or product insert re: Motrin;	
8259	1988	1988 PDR and/or product insert re: Motrin;	
8260	1989	1989 PDR and/or product insert re: Motrin;	
8261	1990	1990 PDR and/or product insert re: Motrin;	
8262	1991	1991 PDR and/or product insert re: Motrin;;	
	1992	1992 PDR and/or product insert re: Motrin and/or Pedia-Profen	
8263	1993	1993 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8264	1994	1994 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8265	1995	1995 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8266	1996	1996 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8267	1997	1997 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8268	1998	1998 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8269	1999	1999 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8270	2000	2000 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8271	2001	2001 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8272	2002	2002 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8273	2003	2003 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8274	2004	2004 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8275	2005	2005 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8276	2006	2006 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8277	2007	2007 PDR and/or product insert re: Motrin and/or Pedia-Profen;	
8278	2008	2008 PDR and/or product insert re: Motrin and/or Pedia-Profen;	

Exh No.	Date	Description	Defendants' Objections
8279	1994	1994 Warning label/insert for prescription Children's Motrin;	
8280	1995	1995 Warning label/insert for prescription Children's Motrin;	
8281	1996	1996 Warning label/insert for prescription Children's Motrin;	
8283	1997	1997 Warning label/insert for prescription Children's Motrin;	
8284	1998	1998 Warning label/insert for prescription Children's Motrin;	
8285	1999	1999 Warning label/insert for prescription Children's Motrin;	
8286	2000	2000 Warning label/insert for prescription Children's Motrin;	
8287	2001	2001 Warning label/insert for prescription Children's Motrin;	
8288	2002	2002 Warning label/insert for prescription Children's Motrin;	
8289	2003	2003 Warning label/insert for prescription Children's Motrin;	
8290	2004	2004 Warning label/insert for prescription Children's Motrin;	
8291	2005	2005 Warning label/insert for prescription Children's Motrin;	
8292	2006	2006 Warning label/insert for prescription Children's Motrin;	
8293	2007	2007 Warning label/insert for prescription Children's Motrin;	
8294	2008	2008 Warning label/insert for prescription Children's Motrin;	
8295	1989	1989 Warning label/insert for Pedia-Profen	
8296	1990	1990 Warning label/insert for Pedia-Profen	
8297	1991	1991 Warning label/insert for Pedia Profen	
8298	1992	1992 Warning label/insert for Pedia Profen	
8299	1993	1993 Warning label/insert for Pedia Profen	
8300	1994	1994 Warning label/insert for Pedia Profen	
8301	1995	1995 Warning label/insert for Motrin in foreign countries	Lacks authentication (Rule 901)
8302	1996	1996 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8303	1996	1996 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
8304	1997	1997 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8305	1998	1998 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8306	1999	1999 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8307	2000	2000 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8308	2001	2001 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8309	2002	2002 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8310	2003	2003 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8311	2004	2004 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8312	2005	2005 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8313	2006	2006 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8314	2007	2007 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8315	2008	2008 Warning label/insert for Children's Motrin in foreign countries	Lacks authentication (Rule 901)
8316	2006	2006 Warning label required by the FDA for OTC ibuprofen products	Lacks authentication (Rule 901)
8317	2005	Warning label required by the FDA for Children's Motrin after the response to Citizen's Petition of 2005;	
8318	2006	2006 Warning label/insert/PDR required by the FDA for prescription Children's Motrin after the Citizen's Petition of 2005;	
8319		All prescription Children's Motrin warning labels/inserts/PDR references 1994 - 2008 ;	Lacks authentication (Rule 901)
8320	2005	Warning label/insert/PDR references for Motrin required by the FDA after the Citizen's Petition of 2005;	
8321		Physician Desk Reference warnings regarding ibuprofen 1978 - 2008	Lacks authentication (Rule 901)
8322		Adverse event reports/med watch forms relating to Kiley Wolfe.	Lacks authentication (Rule 901)
8323		All other pertinent adverse event reports/med watch forms.	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
8324		All product recalls by Johnson and Johnson, McNeil, and/or Depuy.	Lacks authentication (Rule 901)
8325		All warning letters from the FDA to Johnson and Johnson and/or McNeil	Lacks authentication (Rule 901)
8326		"Food Drug & Cosmetic Act" 21 CFR	
8327		Summary documents	Lacks authentication (Rule 901)
8328		Timeline(s)	Lacks authentication (Rule 901)
8329		Illustrations	Lacks authentication (Rule 901)
8330		Spreadsheet(s)	Lacks authentication (Rule 901)
8331		Spreadsheet regarding warning labels,	Lacks authentication (Rule 901)
8332		Charts/Spread Sheets	Lacks authentication (Rule 901)
8333		Time lines	Lacks authentication (Rule 901)
8334		All 55,000 case record of those who took Motrin in the Boston University Fever Study	Lacks authentication (Rule 901)
8335	4/7/2005	April 7, 2005 FDA news release announces that FDA is "asking manufacturers of OTC NSAIDs to include warning about potential skin reactions (Samaras report)	
8336		Christmas list	Lacks authentication (Rule 901)
8337		Documents related to doctor payoffs/kickbacks	Lacks authentication (Rule 901)
8338		Documents related to "Phantom Recall".	Lacks authentication (Rule 901)
8339		Documents related to "40 plus product recalls"	Lacks authentication (Rule 901)
8340		Legal definition of "malice" the intent, without just casue of reason to commit a wrongful act that will result in harm to another.	
8341		Legal definition of "evil intent" - malice law - the state of mind with which an act is committed and from which the intent to do wrong my be inferred	
8342		Warning letter from FDA - re: violations and failure to correct violations at McNeil's plant/plants.	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
8343		Johnson and Johnson's financials, profits, etc.	Lacks authentication (Rule 901)
8344		Johnson and Johnson's corporate structure and its family of companies	Lacks authentication (Rule 901)
8345		McNeil's corporate structure, how it related to Johnson and Johnson and the entire Johnson and Johnson family of companies	Lacks authentication (Rule 901)
8346		Records of Johnson and Johnson acquisitions of companies	Lacks authentication (Rule 901)
8347		Documents of McNeil and/or Johnson and Johnson licensing marketing rights to children's Motrin	Lacks authentication (Rule 901)
8348		Documents regarding Risperdal antipsychotic litigation;	Lacks authentication (Rule 901)
8349		Documents regarding Depuy hip recall litigation;	Lacks authentication (Rule 901)
8350		Documents regarding stop infant drops with acetaminophen;	Lacks authentication (Rule 901)
8351		Documents regarding clinical trial deaths and compensation in India;	Lacks authentication (Rule 901)
8352		Documents regarding kickbacks to doctors in Iran;	Lacks authentication (Rule 901)
8353		Documents regarding Louisiana \$257,000,000.00 judgment	Lacks authentication (Rule 901)
8354		Documents regarding Johnson and Johnson turn its back on Aids patients	Lacks authentication (Rule 901)
8355		Documents regarding Johnson and Johnson violating foreign corrupt practices act abroad	Lacks authentication (Rule 901)
8356		Documents regarding bribery by Johnson and Johnson across two countries;	Lacks authentication (Rule 901)
8357		Documents regarding Johnson and Johnson fined \$70 million for overseas bribes;	Lacks authentication (Rule 901)
8358		Sreadsheet regarding PDR's, packaging inserts and any and all warnings regarding, Motrin, Peda-Profen, Children's Motrin, including OTC warnings and prescription product warnings, foreign and/or domestic for any time period including but not limited to 1978 to the present.	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
8359		Summary, Timeline, Illustration, Spreadsheet(s) regarding John and Johnson/McNeil product recalls, fines, penalties, warning letters, admonitions, judgments and/or any type of wrongdoing of Johnson and Johnson and/or McNeil including, but not limited to adverse judgments, fines by government or otherwise product recalls, penalties, phantom recall, other recalls, actions by congress and/or any congressional committee, warning and/or warning letter by the FDA and any adverse determination by the Government or any Government agency or group or committee, as well as any information regarding, kickbacks, payoffs, bribery or anything of such nature.	Lacks authentication (Rule 901)
8360		Summary, Timeline, Illustration, Spreadsheet(s) regarding Johnson and Johnson/McNeil or any of the Johnson and Johnson family of companies regarding Johnson and Johnson/McNeil or Johnson and Johnson and its family of companies' actions, acquisitions, interrelationships.	Lacks authentication (Rule 901)
8361		Summary, Timeline, Illustration, Spreadsheet(s) regarding Johnson and Johnson/McNeil and/or any or all of the companies in Johnson and Johnson's family of companies' profits and/or losses, earnings, and Financial Statements and/or any other Financial information for all time periods including but not limited to 1978 to the present.	Lacks authentication (Rule 901)
8362		All discovery responses of Defendants	
8363		All of Johnson and Johnson/McNeil's answers to interrogatories as well as amended answers to interrogatories on behalf of Johnson and Johnson, McNeil, William Weldon, Ms. Googing, Anthony Temple, or any other person or entity on whose behalf answers to interrogatories and/or amended answers to interrogatories were submitted.	
8364		Other Summary, Timeline, Illustration, Spreadsheet that would incorporate other Exhibits listed by Plaintiff/and/or defendant (s) on either or both exhibit list.	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
8365		Documents relating to product recalls.	Lacks authentication (Rule 901)
8366		Documents relating to 70 million dollar fine and/or fine or penalty for kickbacks, bribes and/or payoffs .	Lacks authentication (Rule 901)
8367		Documents regarding phantom recalls and/or Congress's/Congressional Committee's and/or FDA's Responses and/or Actions regarding same.	Lacks authentication (Rule 901)
8368		Consent decree regarding phantom recall.	Lacks authentication (Rule 901)
8369		Letters by Congressman Darrell Issa to and from the FDA and/or Johnson and Johnson and/or McNeil regarding uncategorized consent decree Darrell Issa FDA, Johnson and Johnson, Margaret Hamborg, McNeil Consumer Healthcare Motrin regarding phantom recall	Lacks authentication (Rule 901)
8370		Documents regarding Johnson and Johnson creating a reserve for Risperdal settlements.	Lacks authentication (Rule 901)
8371		Documents regarding Johnson and Johnson Depuy and the Hip Implant recall and the Hip Implants.	Lacks authentication (Rule 901)
8372		Documents regarding all product recalls by Johnson and Johnson and/or any of Johnson and Johnson family companies at and time including from 1995 to the present time.	Lacks authentication (Rule 901)
8373		Documents regarding Johnson and Johnson or any of its family of companies Ending Infant Drops with Acetaminophen.	Lacks authentication (Rule 901)
8374		Documents regarding clinical trial deaths and compensation (or lack thereof) in India, and Johnson and Johnson failure to compensate for said death in accord with the law.	Lacks authentication (Rule 901)
8375		Documents relating to William Weldon's compensation for the years 2000 - 2011.	Lacks authentication (Rule 901)
8376		Documents regarding Johnson and Johnson and/or any of its family of companies - refusal to participate in the medicines patent pool, which is an initiative designed to streamline patent licensing for producing genetics of patented HIV medications and offering lower prices in poor countries, plus any letters regarding same by "Doctors Without Borders".	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
8377		Documents regarding Johnson and Johnson's bribery charges across multiple countries and two continents and claims of its violation of the "Foreign Corrupt Practices Act" - and documents regarding the \$70 million dollars that Johnson and Johnson has/had to pay after the company admitted it bribed doctors in Europe and paid kickbacks in Iraq to win contracts and sell drugs and artificial joints - and Johnson and Johnson subsidiaries paid bribes to doctors and hospital administrators in Greece, Poland and Romania.	Lacks authentication (Rule 901)
8378		Documents regarding payoff/kickbacks/bribes to doctors and/or Hospitals in the USA.	Lacks authentication (Rule 901)
8379		A copy of the "Foreign Corrupt Practices Act" (FCPA)	
8380		Documents regarding claims and resulting verdict for 257 million dollars against Johnson and Johnson and any of its family of companies regarding fraudulent billing to medicaid and/or medicare.	Lacks authentication (Rule 901)
8381		Documents regarding Johnson and Johnson reorganizing its McNeil Consumer Healthcare Unit.	Lacks authentication (Rule 901)
8382		Documents relating to a consent decree between Johnson and Johnson/McNeil and the FDA.	Lacks authentication (Rule 901)
8383		Documents regarding Johnson and Johnson/McNeil's transforming McNeil into a separate entity pursuant to a consent decree with the FDA. Said transformation to be official on April 4, 2011 or 2012.	Lacks authentication (Rule 901)
8384		Any and all documents regarding to any consent decrees by Johnson and Johnson/McNeil or any other of the Johnson and Johnson family of companies.	Lacks authentication (Rule 901)
8385		Documents relating to anything of value given to medical entities and/or doctors, from Johnson and Johnson and/or any of its family of companies or anyone or any entity on Johnson and Johnson's behalf.	Lacks authentication (Rule 901)

Exh No.	Date	Description	Defendants' Objections
8386		Documents regarding off label use of and/or prescribing of Risperdal or any other antipsychotics and/or the payment of anything of value to doctors, hospitals, medical facilities and/or Juvenile Detention Centers for the prescribing of any drugs, including but not limited to Risperdal, any other antipsychotic and/or any other medication and/or drug.	Lacks authentication (Rule 901)
8387		Portions of the transcript from previous Children Motrin cases against Johnson and Johnson and/or McNeil, including but not limited to the case of Brianna Maya vs. Johnson and Johnson, and/or McNeil.	Lacks authentication (Rule 901)
8388		Any documents relating to doctors and/or medical facility payoffs, kickbacks, etc. fraudulent billing, failure to compensate those participants who died in clinical trials, any inappropriate actions and/or inactions regarding the proper dispensing and/or marketing of any drug or device.	Lacks authentication (Rule 901)
8389		Documents regarding Johnson and Johnson or Synthes and/or Norain Synthes.	Lacks authentication (Rule 901)
8390		Books, financial statements, income statement, profit and loss statements and any other financial data for Johnson and Johnson, McNeil Pharmaceuticals, McNeil, and all McNeil entities for the years 1990 to the present.	Lacks authentication (Rule 901)
8391		Books, financial statements, income statement, profit and loss statements and any other financial data for Janssen Pharmaceutical, Ortho-McNeil Pharmaceutical and Centocor.	Lacks authentication (Rule 901)
8392		All warning label, package inserts, and any and all warnings in the U.S., and any other country in the world for the sale of Motrin and Children's Motrin.	Lacks authentication (Rule 901)
8393		All documents relating to Johnson and Johnson signature of Quality Program - instituted by Johnson and Johnson in 1992.	Lacks authentication (Rule 901)
8394		Photographs of Kiley Wolfe and her family.	
8395		Stipulation by McNeil and Johnson & Johnson regarding corporate form	
8396		Documents relating to McNeil and Johnson & Johnson corporate form	Lacks authentication (Rule 901)